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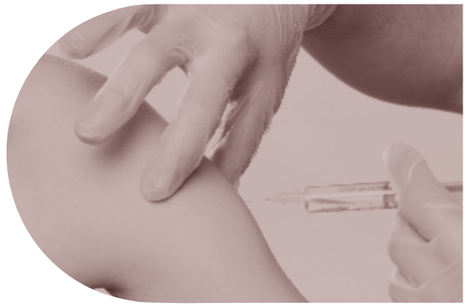
MANIFESTO

Good Distribution Practice Universal Compliance Initiative

Aimed at the entire pharmaceutical distribution chain, the GDP Universal Compliance Initiative is an industry-owned and industry-led undertaking with the aim of bringing certainty, consistency, and continuous improvement to the process of meeting international quality and regulatory standards for the safe, efficient and sustainable distribution of medicines and vaccines.



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preface

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This Manifesto describes a collaborative model for GDP that will build on current quality and risk-management best practices and modernise the GDP process by applying evidence-based improvements to the medicine distribution process.

Overview

Recent research[2] indicates a huge and growing demand for more harmonised distribution compliance across international borders as products become more labile and expensive, supply chains become increasingly convoluted and diverse, and both drugs and their delivery increasingly become the targets of criminal intent.

And with with legal liability for good distribution practice (GDP) compliance starting to extend into the heart of the pharma distribution chain, the added complexity that this engenders needs to be countered by harmonising and simplifying the compliance process at the point of execution.

To this end, a large network of stakeholders in the global pharmaceutical supply chain has come together with the objective of designing and executing a global GDP compliance program that advantageously 'joins up' the profusion of stakeholders, regulations, and quality processes that constitute the pharmaceutical distribution chain.

It can perhaps best be described as a 'bottom-up' approach to GDP since its principal focus is one of interpreting the various GDP regulations and aiding adherence at the operational level rather than one of campaigning for legislative changes or stepping on the toes of established agents-for-change that are already operating in this field.

With no chain being stronger than its weakest link, it is paramount that everyone involved in the storage and movement of vaccines and medicines adheres to common and compatible rules, standards and procedures irrespective of where they are operating. Such an all-inclusive, collaborative approach to pharmaceutical distribution is the only way to safeguard and enhance public health while synchronously improving efficiency.

GDP·UCI - Filling an Unmet Need

Pervasive supply chain fragmentation and complexity, local and regional regulatory divergence, differing interpretations of GDP guidelines, and inconsistent auditing and enforcement processes all add up to an environment that is not especially conducive to continuously improving the safe and secure distribution of life-critical medicines.

It is abundantly clear from research and feedback that supply chain confusion and impediments concerning GDP abound and there is a pressing need for an inclusive and industry-driven GDP-focused support landscape to accommodate fast changing industry and regulatory needs.

While the GMP/GDP harmonisation and alignment work that is being undertaken by a number of established bodies is fully recognised and supported, there are fundamental differences in terms of both object and approach in comparison with GDP·UCI. In particular, the GDP·UCI explicitly involves the entire pharma supply chain with all GDP stakeholders directly and democratically participating in program development and execution. This across-the-board 'hands-on' involvement is crucial since it is during the implementation phase that most of the problems with GDP compliance emerge.

Independence and Impartiality

GDP·UCI has been conceived as a fully independent, industry-owned project. This intrinsic neutrality is essential since the validity, recognition and acceptance of regulatory compliance guidance and supply chain alignment is wholly contingent on the objectivity, integrity, and freedom of vested-interest, of all parties involved.

Structure & Governance

An organic organisational-structure has been created built around Primary Work Groups supported by an expert Advisory Board and an extensive matrix of Special Interest Groups. The entire framework resides on a dedicated web-based collaboration platform.

A democratic Governance Council forms the top tier in the GDP·UCI hierarchy and is responsible for high-level policy, strategic and constitutional issues. Terms of Reference for the Council and its protocols have been agreed and codified as part of the program's Framework of Rules & Regulations.

Target Audiences

The audience for the GDP·UCI program is the entire pharmaceutical supply chain including licensed manufacturers / intermediaries and their upstream- and downstream logistical and service suppliers. The former being where the GDP responsibility ultimately rests and the latter being where most of the current confusion/ inefficiencies exist and where GDP compliance is most desultory.

Project Scope

The inter-related nature of all the different facets of GDP means that the amplitude of the GDP·UCI program is necessarily broad in order to encompass all the operational aspects of GDP compliance at a grass-roots level.

The GDP-UCI remit is, inter alia, one of harmonising the interpretation of GDP guidance, introducing GDP-compliant processes and solutions, synchronising and standardising GDP training / auditing / certification etc. all based, wherever possible, around a credo of commonality and sharing. The scale of challenge this represents is not underestimated which is why the GDP·UCI is:

- courting continuous input from the field
- pursuing a step-by-step approach initially focused on identified GDP 'pain-points'
- seeking working partnerships with congruous institutions and relevant statutory authorities

Industry Consultation / Engagement

A joined-up global GDP compliance system such as GDP·UCI can only be instituted assiduously and expeditiously through the voluntary and democratic involvement of an appreciable number of GDP stakeholders in as many national and zonal jurisdictions as possible. This collaborative imperative is why a unique geographically- and structurally-representative 'Consultation Cluster' lies at the heart of the GDP·UCI program.

WHAT GDP-UCI IS NOT…

The GDP-UCI is not an attempt to rewrite the regulations relating to good distribution practice. The role of developing, authoring and enacting state, national and supra-national GDP regulations and other statutory instruments is the preserve of the relevant legislative agencies.

Furthermore, GDP-UCI is not a vested-interest grouping of any kind and, while pushing the benefits of GDP and facilitating regulatory compliance, is not promoting, protecting or controlled by, any specific business interests or factional groups.

"Logistics networks are becoming increasingly complex as ever more environmentally astute technology is developed and demand for biologics and pharmaceuticals from emerging markets such as Asia and Africa continues to rise and next generation cell and gene therapies are brought to the market"[1]

1. introduction

The logistics associated with the safe and efficient physical transportation of pharmaceuticals is increasingly taxing the minds of logisticians as medicines become more complex and physically temperamental and as their regulatory oversight intensifies. The statutory need to maintain the therapeutic and physical integrity of drugs during transit as well as their identity and security renders the management of quality and the adherence to good distribution practice (GDP) guidelines as an absolutely critical part of the pharmaceutical supply process.

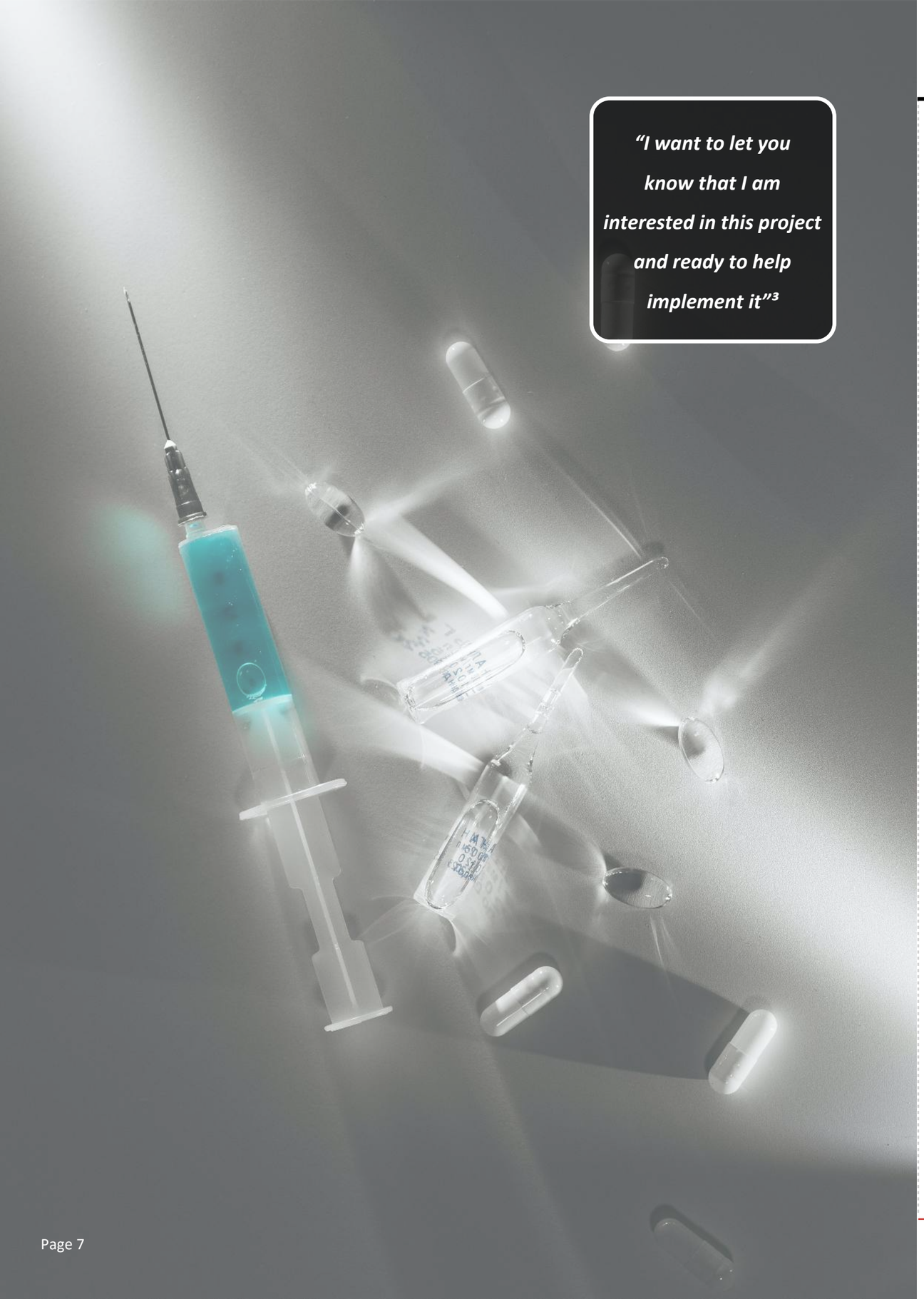
Research[2] shows there is an overwhelming recognition of the need for a more joined-up approach to pharmaceutical Good Distribution Practice and a pressing need for regulatory compliance to reflect rapidly changing market realities.

To fill this gap a group of leading pharmaceutical supply-chain stakeholders has come together to generate an independent Good Distribution Practice (GDP) program to champion the development, harmonisation, standardisation and simplification of global GDP practices.

The GDP·UCI program is aimed at pharmaceutical manufacturers and the entire distribution chain and being designed to bring consistency, certainty, and continuous improvement to the complex process of meeting international quality and regulatory standards for the safe, efficient, and sustainable distribution of medicines, vaccines, and APIs.

For this to happen a new relationship between stakeholders in the pharmaceutical supply chain is necessary. Only a collaborative 'by-the-industry, for-the-industry' approach built around the principles of collaboration and mutual consensus can take us directly to the ultimate goal of enhanced patient safety.

It is time for the industry to come together. This Manifesto describes a collaborative model for GDP that will build on current quality and risk-management best practices and modernise the GDP process by applying evidence-based improvements to the medicine distribution process.



"I want to let you know that I am interested in this project and ready to help implement it"[3]

2. background

Good distribution practice (GDP) describes "the minimum standards that must be met to ensure that the quality and integrity of medicines is maintained throughout the supply chain".[4]

Compliance with GDP ensures that:

- medicines in the supply chain are supplied in accordance with prevailing legislation
- medicines are stored in the right conditions at all times, including during transportation
- contamination by, or mix up with, other products is avoided
- an adequate turnover of stored medicines takes place
- the right products reach the right addressee within a satisfactory time period
- Product traceability is maintained from manufacture to patient

GDP as a quality discipline is a progeny of Good Manufacturing Practice (GMP) which in turn emanated from the consumer protection movements which began to emerge in the US and Europe in the early 1900s. Many of the original rules for drug safety and all the subsequent drug manufacturing (GMP) edicts that followed, were put in place in response to events such as the shocking thalidomide disaster of the late 1950s and early 1960s.

A full suite of 'GxP" guidelines are now in force in many jurisdictions around the world and these cover nearly all stages of the life-cycle of a pharmaceutical product from development to distribution. In addition to finished commercial drugs, the guidelines cover APIs and clinical trials, both veterinary and human.

However, despite its common origin GDP is fundamentally different from GMP in that with the latter there is near full control of processes and risks whereas in the former the processes involved largely take place outside the direct control of the manufacturer and involve numerous organisations of varying competence and expertise.

These supply chain inter-dependencies often manifest themselves in a high number of sub optimal interactions and unaccountable errors which can be difficult to address without breaking down the classic silo cultures that characterise many relationships.

The physical distribution of medicines from the point of manufacturer to the point of consumption is an exacting process. The distances involved are often huge and can be tens of thousands of kilometres, the time-scales can be long, sometimes extending into years, and the number of different organisations involved can run into the dozens.

The challenges of GDP include the fact that it is usually impossible to tell visually whether a drug has been substituted, contaminated or lost clinical potency during its storage or transportation.

Another area of enormous concern is the growing incidence of drug counterfeiting which has become a massive underground industry and an equally massive patient-safety issue. This alarming trend has been the catalyst for the introduction of serialization and traceability legislation and systems in order to verify drug source and authenticity Examples include the U.S. Drug Supply Chain Security Act (DSCSA) and the E.U. Falsified Medicines Directive (FMD).

The GDP Triumvirate

There is no single global GDP standard. The US, The EU and the WHO each have their own discrete guidelines and there has been a trend for different countries and trading blocs to develop their own distribution guidelines often based, sometimes loosely, on one or other of these core renditions. The net result is a patchwork of broadly comparable, yet not identical, standards that only serves to foment confusion, increase cost and magnify risk.

One thing that is common to the three main regulatory frameworks, however, is their convoluted enactment. For example, in the US some GDP regulations are applied at a federal level while others are reserved for the states.

On the other hand, in Europe the GDP regulations were put in place in the form of a Directive which means that although they are intended to be applied in a consistent way, in practice they are open to wide interpretation. By the same token, the WHO GDP guidelines, unless adopted into a country's legal framework, are neither statutory nor independently enforced.

On a positive note, the fact that the technical content of the main GDP regulations is broadly similar means that many of the challenges ahead for GDP·UCI will relate more to the harmonised interpretation, guidance and enforcement of the guidelines than in the origination of new ones.

A blanket Mutual Recognition Agreement (MRA) is currently not in place between the US and EU when it comes to GDP although it is safe to say that, for the most part, the EU GDP is viewed as the 'gold standard' on both sides of the Atlantic. Some sharing of information between Europe and the US does take place however.

As far as inspections are concerned, the FDA has the authority under the 2012 Food and Drug Administration Safety and Innovation Act, to enter into agreements to recognize drug inspections conducted by foreign regulatory authorities if it determines those authorities are capable of conducting inspections that meet U.S. requirements. In this respect MRAs covering inspections are now in place between the FDA, the EU and the UK.

DUTY OF CARE

In this day and age many of those working in the healthcare industry have a legally-enshrined duty-of-care to ensure that their organisation's products perform as expected and do not harm the customer. To discharge this duty the pharmaceutical industry must not only to ensure that effective quality systems are in place but must work, collaboratively where possible, to improve supply chain visibility, nurture supply chain relationships and actively drive continuous improvement.

As far as the physical safety of drugs during transportation is concerned, compliance with GDP generally works fairly well with serious incidents or violations being kept at a fairly low level. But, by any measure, the cost of this quality and integrity assurance is inordinately high and much of the industry has reached the stage where GDP adherence is stuck in a quagmire of grudging tolerance and reactive measures rather than being regarded as a route to sustainable added-value and the achievement of business goals.

RISK FACTORS

The very fact that GDP is essentially a shared supply-chain responsibility renders it a very tough proposition to implement and police in practice. It is hard enough for management to connect the quality management process with the concepts of ‘added value’ and ‘process efficiency’ in a manufacturing (GMP) context where reliable metrics exist, but much harder in the amorphous world of GDP where so many risk factors rest outside its orbit of control.

As a result, the trend towards up-front quality or 'Quality by Design' (QBD) that we have seen take hold on the manufacturing front has not been widely replicated in GDP circles. The prevailing ‘if it ain't broke don't fix it’ mentality only serves to perpetuate a 'just good enough' culture, an attitude which is completely at odds with the ethical standards expected of the life-sciences industry.

To take one example: an over-reliance on drug stability data as a means of surmounting the impact of unwanted temperature excursions during distribution is not always a sensible or efficient means of validating product quality, efficacy and safety. Far better to devise a QMS system that addresses risk at source and eliminates the need for such questionable, costly and resource-intensive post-hoc interventions.

SCOPE

While accepting that the products and circumstances of different drug manufacturers vary widely, this must not be an excuse for ignoring the scope for greater standardisation and harmonisation of risk management systems and procedures. Notwithstanding an infinite spread of distribution scenarios, it should not be forgotten that the vast majority of pharmaceutical products are transported in well-understood risk environments, within a small number of temperature bands and via a limited number of transportation options.

While all distribution quality management systems are going to be necessarily bespoke in some of their aspects, there is little doubt that many of their facets could benefit greatly from a more aligned, inter-connected and co-ordinated approach.

Such a universal QMS architecture would standardise best practice solutions, reduce costs, improve quality, allow universal benchmarking, permit proportionate out-of-specification (OOS) responses and drive continuous improvement. These are all things that the industry is crying out for as recent surveys clearly illustrate.[2]

CONTINUOUS IMPROVEMENT

As the global pharmaceutical industry continues to mutate and we see further seismic changes in the logistics sector, the need for the continuous improvement of distribution practices is going to accelerate.

For example, the growing prevalence of highly highly sensitive biologic medicines, the impact of COVID-19 vaccines and therapies, the accelerating coalescence of medicines and medical devices, the impact of new data technologies, and an explosion of counterfeit products are just some of the challenges for GDP that need to be addressed dynamically.

For these reasons it is time for the industry to move away from today's climate of GDP latency, isolationism and indifference and work together in a more pro-active way to find workable solutions to these unrelenting market shifts and disruptions.

ROLE OF REGULATORY AUTHORITIES

Back in 2001 the EU issued Community Code Directive 83 defining a framework for the harmonisation of the regulations relating to medicines including the rules governing their distribution. As far as Good Distribution Practice is concerned this code built on the original EU GDP Guidelines of 1994 and has culminated in, amongst other things, the revised EU Guidelines of November 2013 for human medicinal products and the Guidelines for APIs of March 2015.

However, although the EU guidelines that were introduced in 2013 have formed a template for many subsequent national regulations, even within the EU the GDP is open to wide interpretation. To a large extent this is because, firstly, GDP is (necessarily) non-prescriptive in nature and, secondly, the Guidance has been enacted in the form of a Community Directive rather than as a Regulation. This places responsibility for interpretation and executions in the hands of 'National Competent Authorities' which govern the authorisation of wholesale distributors and their compliance with the guidelines. In this context it is interesting to note that the EU Drug Regulatory Authority (EUDRA) currently lists no less than 378 National Competent Authorities.

So for now, there is no single global GDP standard despite the harmonisation efforts of bodies such as ICH, and PIC/S (Pharmaceutical Inspection & Co-operation Scheme). There are literally dozens of national and regional GDP standards in operation around the world. And although most of these are similar and are discharged under MAH (Marketing Authorisation Holder) and WDA (Wholesale Dealer Authorisation) type licensing systems, there is much variation when it comes to detail and enforcement.

GDP's EUROPEAN ORIGINS

Regulatory bodies such as FDA and the EU EMA, together with their national networks, have the common goal of ensuring that medical products are 'safe, effective, and appropriate for their intended use'.

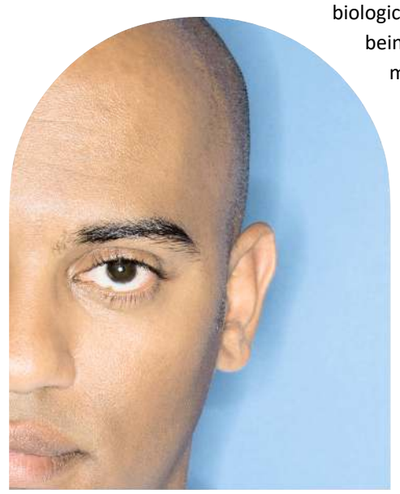
It is important to realise that regulatory authorities require that a manufacturer ensures product quality not just during storage and transport but until the drug concerned is used for patient treatment. For example the International Conference on Harmonisation (ICH) stipulates that that "the storage conditions and the lengths of studies chosen should be sufficient to cover storage, shipment, and subsequent use."[5]

Official guidance in this respect is unequivocal and invariably recommends that drugs that are subjectively judged at point of use to be degraded or out of tolerance should be discarded. For example, the US Centers for Disease Control and Prevention says that it is dangerous to administer vaccines where the temperature history is unknown or uncertain: "It is better to not vaccinate than to administer a dose of vaccine that has been mishandled".[6]

"One of the challenges to standardise global processes is to keep enough flexibility to accommodate different countries/regions requirements without exceeding the logistics costs in small markets."[3]

3. the need

'Pharmaceuticals' are manufactured medical products and preparations used in the diagnosis, treatment, prevention and cure of illness and disease. They can be either chemical- or biological-based with a growing proportion of new drugs being the latter. 'Large molecule' biologics can be much more effective with fewer side effects but at the same time are harder to manufacture and much less stable in use.



The production of these pharmaceuticals is often very large scale, and tends to take place in a relatively small number of global production hubs. The output of these production centres is then distributed widely, often worldwide, with the quality and integrity of the product being maintained through a system of legal standards generally known as good distribution practice (GDP);

However, the logistics associated with the transportation of these sensitive compounds, and their constituent ingredients, is widely characterised by its fragmented nature involving numerous alien actors, and by its sometimes lukewarm approach to regulatory discipline.

The bottom-line is that in order to meet its regulatory obligations, each and every pharmaceutical distributor and logistics company is having to resort to an essentially customised GDP compliance process.

Inevitably this results in procedural inconsistencies and renders GDP outcomes almost impossible to measure and compare. High compliance costs and 'make-do' workarounds are further consequences of what is often an unnecessarily tortuous process.

NEED FOR REFORM

There are several serious and interwoven issues impressing upon the need for reform and integration of the GDP process.

Some of these include:

- **Supply chain fragmentation** - logistics is one of the world' most fragmented sectors rendering it notoriously difficult to control and remodel.
- **Low resilience** - the vulnerability of the pharmaceutical logistics chain to large-scale disruption was cruelly exposed by the COVID-19 pandemic.
- **Cold chain infrastructure** - this exhibits huge variability across countries and markets. The growth of biologics and shifting market demand patterns are putting pressure on the availability of cold storage and bonded warehouse facilities in some regions.
- **Duplication of effort** - collectively the industry unnecessarily replicates an enormous swathe of work especially in relation to asset utilisation and quality compliance, partly on account of a pervasive silo mentality.
- **Security vulnerabilities** - these especially relate to counterfeit product, which is driving strict track & trace legislation.
- **Poor consignment visibility** - this is another product of fragmentation which inhibits dynamic product monitoring and timely interventions.
- **Lack of supply chain transparency** - the industry's congenital 'silo mentality' and protectionism curtails co-operation and suppresses supply chain trust.
- **Training shortages** - Rising standards and regulatory demands have highlighted a dearth of good GDP training in many countries.
- **Sustainability issues** - the carbon footprint of sending medicines, by air especially, is of growing concern.
- **Technical standards** - the absence of common standards is a growing impediment to the driving of sustained improvement across the sector.
- **Escalating shipping costs** - the volatility in freight rates, both air and sea, over the past years has meant that pharmaceutical companies are being forced to look ever more closely at distribution costs.
- **Lack of support** - there is a global dearth of independent and practical GDP compliance guidance and support programs.
- **Poor understanding of quality costs** - although there is a growing awareness of the cost-impacts of regulatory non-compliance the hidden costs of poor quality are neither well understood, nor generally well-documented.

Even where an attempt is being made to ascertain these costs the data can be very nebulous due to widely varying corporate costing and cost-allocation policies.

All of these issues impress upon the need for a more integrated GDP process since it makes no sense at all for each individual pharmaceutical company to be:

- finding, assessing and validating hundreds of different carriers and suppliers
- developing and maintaining dozens of discrete OQ and PQ test protocols
- designing dozens of separate system and product evaluation and qualification programs
- conducting rigorous training programs for a multitude of ever-changing products and pack-out permutations
- producing dozens of separate lane validations
- maintaining dozens of in-house SOPs and KPIs
- using/developing proprietary digital booking and monitoring systems that are not interoperable
- creating their own set of requirements, based on unilateral interpretation of the rules and guidance, which may be at significant variance to those of supply chain partners/customers.

THE COST OF GDP QUALITY

A huge proportion of a pharma company's spend relates to the cost of quality. Yet less than 50 percent of companies in the life sciences industry really know what the COQ is for their organisation[7] and the reality is that poor quality is one of the biggest 'cost icebergs' in business.

GDP is no exception with many, perhaps most, pharma companies not measuring, or being unable to measure, the waste attributable to GDP deficiencies.

Some of the quality-related logistics costs include:

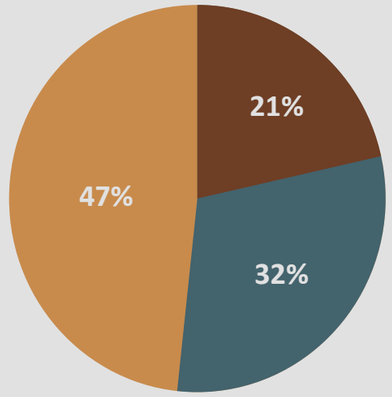
- **Dedicated compliance staff - skilled quality team is expensive**
- **Cost of external consultants - specialised knowledge and independent expertise is expensive**
- **Cost of specialised external facilities - testing houses, cold chambers etc.**
- **Management time - not easily quantified**
- **Validation exercises - including seasonal and recurrent shipping lane validations**
- **Shipping field trials - expensive and time-consuming**

> ***"It is impossible to determine the total cost of compliance accurately due to the fragmentation and complexity of the compliance universe"[8]***

- **Qualification exercises - equipment and packaging, calibrations etc.**
- **Cost of equipment - protective packaging, data loggers, reefers etc**
- **Cost of qualifying equipment and validating processes**
- **Shipment record keeping**
- **Shipment monitoring**
- **Training**
- **IT systems development**
- **Facility upgrades**
- **Opportunity cost from diverting scarce internal resources**
- **Establishing written procedures and SOPs**
- **Cost of deviations - reporting, RCA, CAPA, product waste, delays**
- **Lost customers, delayed market penetration, regulator fines, and other market impacts in the event of quality default.**

Fig. 1

How well does your company understand the total costs of GDP compliance that it is exposed to, including those costs that are 'hidden' ?



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47	We have a good idea of our direct GDP compliance costs such as manpower and auditing, but hidden and shared costs/budgetary data are not readily available.
32	We have a clear understanding of all the direct, indirect and incremental costs relating to compliance including the cost impacts of remedial / RCA / CAPA reporting and other non-conformance disruptions.
21	Not very well. The costs of GDP compliance are not readily identifiable in our system.

More than two-thirds of shippers and LSPs having little or no idea what their real costs of GDP are. This finding represents one of the most compelling reasons for reform in the field of supply chain management and quality control.

The fact is that, although there will always be a need for specialist transport arrangements for niche, very sensitive, and potentially dangerous pharmaceuticals, the vast majority of bulk prescription medicines and vaccines are:

a. distributed within a small handful of recognised temperature bands and storage environments, and

b. transported by a network of logistics providers that are GDP-obligated but, at the same time, constrained by practical and economic constraints as to the degree of client-specific customisation they can provide.

We have seen that in practice GDP guidelines are adopted and enforced in many different ways. The only way to address this is to level the playing field through the development and adoption of best-practice procedures, solutions and standards that are accepted universally and embraced internationally.

FIT FOR PURPOSE?

Although global Good Distribution Practice (GDP) regulations are observed and enforced with varying degrees of rigour, they are generally quite clear at a macro level with respect to the outcomes required and where ultimate responsibility and accountability rest.

It is during the implementation phase that some of the most intractable problems with GDP compliance emerge, often:

- as a result of supply chain fragmentation and complexity
- because of local and regional regulatory dissimilarities
- because of the scope for different interpretation
- because the auditing and enforcement process differs between jurisdictions.

So the seemingly simple process of ostensibly keeping medicines within ‘label claim’ suddenly becomes a huge challenge. Going forwards, and unless them industry can agree to work in a different way, it is a challenge that is only going to get bigger as we move towards a greater proportion of biologics and increasingly complex medicines.

"We all know the GDP theory. It's applying it that creates problems"[3]

4. the opportunity

The disruptions that the pharmaceutical supply chain continues to experience in the wake of the Covid-19 pandemic has created a huge incentive for pharmaceutical manufacturers and their logistics providers to come together in win-win GDP partnerships that can assure and improve drug delivery into the future.

The inefficiencies and isolationism that continue to bedevil the GDP compliance process are firmly embedded and are not going to be solved by individual actors working, however frantically and intensely, in isolated silos. Optimum solutions can only be found through the alignment of the interests of multiple parties in which individual self-interest feeds into the common good.

The industry's key GDP stakeholders must come together and take the opportunity to harness the forces for change that are evident in order to push the changes necessary to fill the void in the market for a more universal, harmonised and standards-driven approach to quality, qualification and training in the distribution of medicines. For this multi-party alignment we need common-purpose, strong co-ordination and mutual commitment.

Any long-term solution needs to be highly integrated and include the development and joining up of GDP compliance, operating procedures and digital technologies. Such a systemic approach requires universal standards, technical interoperability and a much greater uniformity of process. Critically, it also needs a shift in business-culture based around a better understanding of the GDP 'big picture' and a readiness to share and collaborate more closely towards common goals.

A more collaborative GDP model will:

- Bring all GDP stakeholders together to share knowledge, ideas and resources, minimise process divergence and collectively innovate.
- Greatly simplify the GDP quality compliance and enforcement processes.
- Remove huge amounts of duplicated effort, overlap and repetition amongst pharmaceutical companies and supply chain actors.
- Proactively attenuate some of the avoidable risks inherent in the pharmaceutical logistics process.
- Introduce standardisation of player, process, product and system.
- Raise standards by reducing the high number of quality and regulatory non-conformancies.
- Provide shippers and LSPs with common reference points for continuous improvement in quality and compliance.
- Reduce costs as a result of standardisation and economies of scale.

It is firmly believed that the only way that a joined-up global GDP compliance system like GDP·UCI can be created is through a system of shared vision, cultural alignment and voluntary co-operation from all parties and hierarchies concerned. Such a collaboration needs sweeping industry involvement and a preparedness to compromise if necessary. The structure of the GDP-UCI is geared in this direction. See Section 9 Page 50.

APPENDIX 3 Page 71 contains a list of the organisations formally registered in the GDP-UCI project as at December 2022. and committed to participating in the program development. A graphic showing the breakdown by organisational category is also shown in APPENDIX 4 Page 75.

Summary

By taking a holistic approach to GDP and by taking into account the positions and viewpoints of all GDP stakeholders, the GDP·UCI initiative will not only substantially improve compliance with Good Distribution Practice, it will deliver tangible benefits to all those parties that are willing to work together in the common interest.

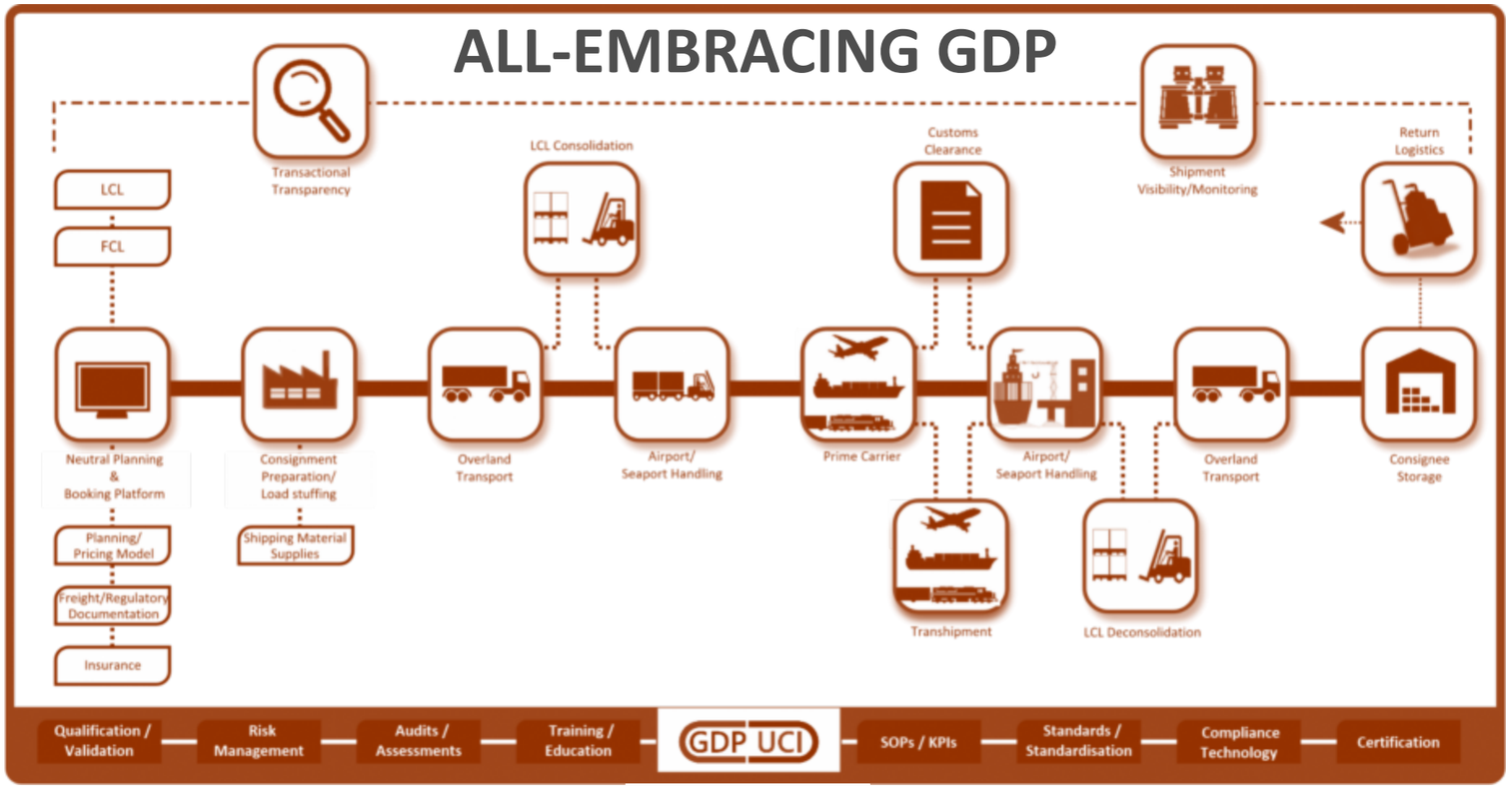


Fig. 2

The GDP·UCI initiative will impact and benefit GDP stakeholders right across the pharmaceutical distribution chain

"I do not believe manufacturers have a robust understanding of the realities of transportation within the freight forwarding arena"[3]

5. target audience

Quality-driven patient safety in all its facets is the responsibility of everyone in the pharmaceutical supply chain. GDP is no exception and there is an onus everyone involved to pursue their moral and legal obligations to the full.

This implicit duty of collective care together with the industry-wide and global ambitions of GDP·UCI render GDP-active and associated parties the target ence for the initiative.

This includes: (but is not limited to)

1. Regulators

It is in the interests of regulators to support the development of a rigorous and independent third-party initiative that furthers the compliance with the regulations that are in place to ensure the safety and efficacy of approved drugs.

Although regulators, as adjudicative bodies, need to maintain a degree of detachment and independence from both the state and the market, there is a need for them to proactively engage with those they oversee. Furthermore, there is a growing trend for regulatory agencies to act in an advisory and enabling capacity in response to increasingly complex regulatory demands.[9]

In terms of GDP, this supportive behaviour can manifest itself in the form of the official support of third-party GDP solutions (e.g. the MHRA's recognition of the Cogent 'Gold Standard' training courses for Responsible Persons)

On the other hand, regulators are under increasing pressures from a resource perspective and this is limiting the degree to which they are able to interact with actors in pharmaceutical supply chains. It is conjectured that, in this respect, the GDP·UCI, as a strong, independent, industry-driven body, could play an instrumental role in fostering relationships and facilitating communications between regulator and industry.

2. Pharmaceutical Companies

One of the problems with GDP in its current form is that it is often operates in a *de facto* vacuum within QA departments where it is viewed by senior management as little more than a non-value-adding embedded cost. This marginalisation of GDP as an externally imposed detriment needs to be contested vigorously.

In other pharmaceutical companies there is sometimes the reverse case in which GDP personnel have imposed upon them the responsibility for transportation strategy and decisions for which they have little, or no, training or competence.

The fact is that GDP needs to be assimilated into mainstream business operations and accorded the status of a value-add process rather than viewed as little more than a 'necessary evil'. Greater recognition needs to be given by senior management of the potential of GDP not only to assure product safety but also to reduce costs, cement supply chain relationships, protect/enhance corporate reputations and secure competitive advantage.

3. Logistics Service Providers (LSPs)

LSPs – forwarders, carriers , handlers, storage providers etc. – have much to gain from being part of a more joined up GDP landscape since the physical activities to which the standards relate largely fall into their remit.

For example, one of the recognised drawbacks of the current GDP process relates to the fact that there is no regulator-recognised compliance certificate for outsourced logistics providers (other than EU WDAs). Another area of contention relates to the multiplicity of shipper audits, of widely varying source, scope, rigour and frequency, to which LSPs are continuously subjected.

Recognition of the need is evident in the current proposals to amend the US FDA 21 CFR 205 federal standard to include the licensure of third-party logistics providers.[10]

4. Equipment Suppliers and Solution Providers

Vendors are often seen as being remote, both physically and legally, from the front-lines of GDP compliance. Yet it is their products and systems that must be selected, tested and qualified as part of validated, GDP-compliant, solutions.

5. GDP Professionals

With GDP as a function often sitting low on the priorities of senior management, many people working in GDP-related positions struggle for internal recognition. Research[2] shows that as many as 20% of GDP-responsible people at pharmaceutical manufacturers, distributors and forwarders do not even consider 'quality' to be a core component of their corporate culture.

Such intransigence and inertia is symptomatic of corporate cultures that view GDP compliance, although a legal obligation, as an unwelcome cost-overhead. This low prioritisation gives management little incentive to change established patterns of behaviour.

in order to attract and retain high calibre staff, the GDP function must be empowered with the necessary respect, status and authority. To this end the GDP-ICU initiative will promote GDP as a worthwhile and valued career option. and provide a platform on which to give GDP practitioners a voice.

6. Government Health Authorities

Although the role of a national health department or Health Ministry may vary from one country or state to another, they are very often the principle responsible authority for the storage and distribution of publicly-supplied medicines and vaccines. In such cases, however, these national supply operations frequently fall outside the control of the appropriate regulatory bodies. This means, for example, that a health department can open a cold storage facility without being approved, checked and monitored.

"Regulatory oversight has contributed to the creation of a risk management and quality culture in the private sector. Although the public sector is the main player at the country level of vaccine management operations, the public sector is mostly untouched by regulatory oversight. The ability to demonstrate compliance with good storage and transport practices shall only be possible with increased regulatory oversight of public sector operations."[11]

This dissociation makes it very important that these powerful departments are brought in to the core of the GDP·UCI project.

Summary

The audience for the GDP·UCI program is the pharmaceutical MAH /WDA community together with the entire pharmaceutical -distribution chain - the former being where the GDP responsibility ultimately rests and the latter being where the majority of GDP-related activities are ultimately carried out.

WHO'S RESPONSIBILITY?

It is the ultimate responsibility of a drug product's Marketing Authorisation Holder (MAH) to ensure that the product placed in the market is safe and effective for use. However, the MAH often relies on a distributor(s) that possesses a wholesale distribution authorisation (WDA) to supply the products to the medical and retail markets and in these cases the responsibility for GDP compliancy passes to the licensed distributor.

GDP puts the responsibility on the MAH or WDA pharmaceutical companies to qualify their suppliers:

"Where contract service providers are used, the wholesaler must make itself aware of the operating procedures of that party (e.g. by audit). This assessment should include examination of the transportation methods and routes. Contracted arrangements for transportation should be documented in a service level agreement, and should include details of any sub-contracting."[12]

But although contractual responsibility for GDP compliance may be shuffled along the supply chain, this does not discharge an MAH or WDA from its overall legal responsibility of ensuring regulatory adherence by its outsourced distribution contractors.

So it is essential that MAHs, WDA holders and the regulators are aware of the GDP·UCI initiative and are prepared to support its collaborative approach to addressing the weakest links in the pharmaceutical distribution chain.

In doing so the GDP·UCI initiative will break the head-in-the-sand intransigence that is weakening GDP accountability and stifling reform.

"The risk levels associated with each step of the supply chain are vastly misunderstood"[3]

6. mission & goals

The following mission statement summarises the purpose and core values of the GDP·UCI initiative:

GDP·UCI PROGRAM MISSION:

"CREATING A JOINED-UP APPROACH TO THE SAFE AND SUSTAINABLE DISTRIBUTION OF MEDICINES FROM PRODUCER TO PATIENT"

Ultimately everyone involved with GDP has the end-goal of improving patient safety and patient outcomes. However to achieve this involves a complex synthesis of many different quality-assurance factors, with adherence to GDP being just one part of the equation.

The GDP·UCI as part of the overall compliance mix has a number of overall goals that make it relevant in a world of rapid change and disruption.

Amongst these is the provision of GDP support and the creation of a logistics standardisation framework that is global, consistent, simplified, standardised, scalable, adaptable and affordable.

Nonetheless, it is important to understand where the boundaries of the GDP-UCI program objectives rest and the reader is referred to the text-box on Page 4 - "What GDP-UCI is NOT" - for further details.

PROGRAM GOALS

1. Impartiality

One of the most important aspects of the GDP·UCI initiative relates to its commercial independence. The program's legitimacy is contingent on it being perceived as 100% impartial and objective so it is essential that the program does not represent, nor is unduly influenced by, any factional interests.

This neutrality and industry-wide scope of GDP·UCI will ensure that it is fair and balanced, amenable to regulatory authorities, not dominated by any vested-interest groups, immune to undue commercial interference, and not in contravention of competition law. This inherent fairness is also vital to the take-up of the program with many companies seeking commercial advantage from adhering to recognised best GDP practices.

2. Universal in scope (multi-modal)

As a GDP initiative that is multi-modal in scope, the GDP-UCI is a very attractive proposition to shippers since it can facilitate the optimum choice and integration of different forms of transport.

3. More than certification

Executed correctly, certification can be a useful tool in the compliance armoury. However, many certification schemes fall short on their primary purpose (See Box, Page 40). In addition to certification, the GDP-UCI program is a single port-of-call for all the other elements of compliance - solutions, standards, training, audits etc.

4. International Industry-Wide Recognition & Legitimacy

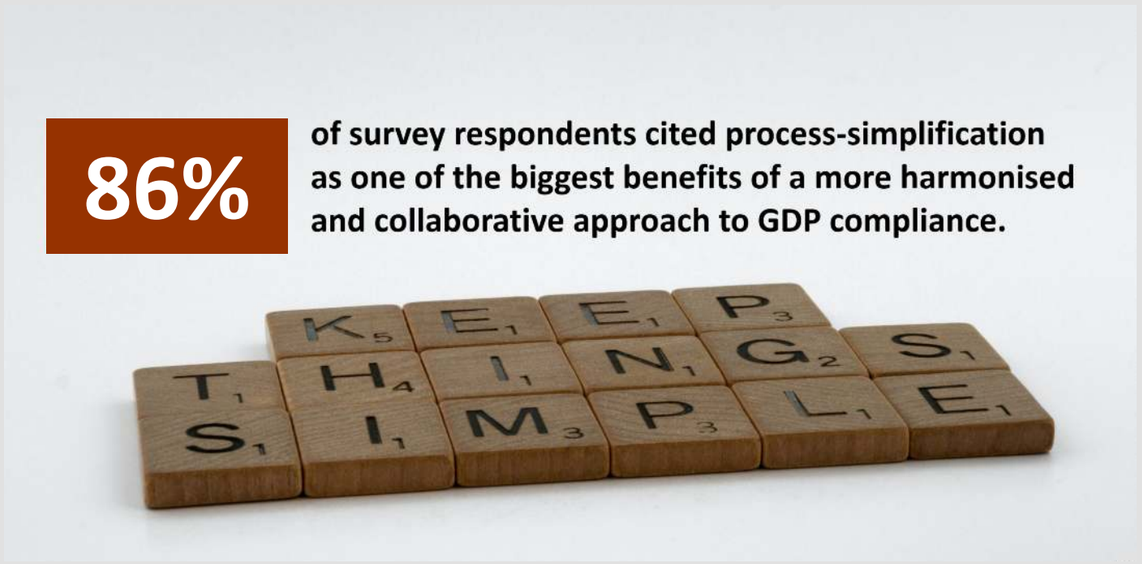
Pharmaceuticals is a global industry and GDP compliance is a universal prerequisite for the correct storage, handling and transportation of medicines and vaccines in all places and under all conditions. Therefore, for maximum effectiveness, the GDP·UCI initiative has taken a global approach to addressing GDP issues in pursuit of industry-wide and international recognition as a benchmark for best practice and regulatory compliance in the distribution of pharmaceuticals.

5. GDP Simplification

You don't have to look very far to find a complex process which has been simplified, at least from a user's perspective, to tremendous effect. A classic and contemporary example from logistics is Amazon. Jeff Bezos made himself arguably the world's richest man through an obsession with simplifying the customer experience through a quick, safe, no-stress internet buying process.

Fig. 3

GDP SIMPLIFICATION



The logic behind Amazon' simplification business model applies every bit as much to pharmaceutical logistics where the complexity and fragmentation of the logistics machine can only be controlled through a consensus approach and the judicious application of enabling technologies.

Simplification of Pharma GDP

Simplification brings huge advantages: it increases agility and responsiveness, removes margins for error, reduces bureaucratic bottle necks, promotes efficiency, fosters transparency, clarifies risk, creates competitive advantage and reduces costs.

6. Certainty, Uniformity and Universality

The countless permutations of different GDP approaches needs to be replaced with a comprehensive compliance model that is adaptable, scalable and universally accessible.

GDP·UCI will provide GDP certainty, consistency and peace of mind throughout the pharmaceutical distribution chain. The current disjointed and fragmentary nature of pharmaceutical logistics can only be solved through the adoption of consensus solutions based on greater standardisation and harmonisation.

7. Harmonisation of core GDP Practices

The concept of 'bottom-up' operational homogeneity is at the very heart of the GDP·UCI program. At a macro, industry level global GDP harmonisation and mutual recognition is the preserve of bodies such as ICH, WHO, PIC/S etc. Unfortunately this supranational mission is a long and tortuous undertaking that will take many more years to bear fruit. Meanwhile, and arguably more pressing and directly impactive, is the need for greater GDP clarity and harmonised guidance at the operational front-line.

8. Value and Affordability

"The costs of poorly managed quality and lax regulatory compliance within the logistics chain will always end up at the door of the client in some shape or form. Usually with an enormous price-ticket attached."[13]

It is accepted wisdom that an investment in improving quality will almost invariably eclipse the costs of poor quality. For example, while the over-riding goals of GDP·UCI relate to improving pharmaceutical distribution with respect to patient safety, this can only be achieved through making the entire distribution process more efficient, more simplified, more homogeneous, more consistent and more measurable. In turn, these will translate into meaningful cost savings and operational improvements.

It therefore safe to say that with so many systemic shortcomings in evidence it is entirely reasonable to expect significant value-for-money benefits from the proposed program. For example, it is not hard to envisage how a more standardised and integrated approach to GDP will eat into the substantial costs inherent in the regulatory reporting, assessment and CAPA activities associated with temperature deviations.

A more efficient, structured compliance system will not only reduce the costs of compliance right along the logistics value-chain but ensure wider program take-up. See 4. above. And with more than two-thirds of shippers and LSPs having little or no idea what their real costs of GDP are (Fig.1) the GDP·UCI will endeavour to bring greater understanding of the scale of costs relating to non-compliance.

The benefits of quality in general and of GDP compliance in particular need to be established from both a quantitative and qualitative perspective otherwise referred to, respectively and more prosaically, as the return on investment and return on expectation. Such a holistic evaluation of the net yields from the pursuit of purposeful GDP, taking into account expected short and long-term returns and both tangible and intangible benefits, is a key objective of the GDP·UCI program.

9. Protecting the right to operate

High costs of compliance will always be a barrier to attaining improved standards of distribution. Yet a failure to invest adequately in GDP can be disastrous. If an organisation doesn't invest properly in GDP compliance it compromises its business prospects, or even its very existence if it loses the necessary authorisation to operate. On the other hand, adherence to a structured and rigorous GDP·UCI agenda demonstrates a tangible real commitment to best practice and continuous improvement.

In the case of pharmaceutical companies the membership of GDP-UCI confers legitimacy in the eyes of the regulator, and for supply chain actors it is a means of showing they are committed to conducting their operations safely, competently, and compliantly.

10. Adaptability

The GDP·UCI configuration has the flexibility and versatility to cope with rapidly changing market conditions, to align with national GDP variants, to react to technical and market disruptions, and to be relevant to different freight modes, corporate structures and business priorities.

11. Accessibility

GDP·UCI must be designed and structured to be accessible, through appropriate platforms, technologies and partners, to all interested parties in all regions in the world.

12. Sustainability

Sustainability has become an intense global priority and rests at the core of the GDP·UCI project rather than as a perfunctory afterthought. Environmental performance will be a paramount and obligatory consideration when developing GDP solutions.

13. Scale and Scalability

Being global in scope, the GDP·UCI is being designed for rapid scalability to meet demand and future growth.

14. Partnerships

With its goal of improving, consolidating and standardising the pharmaceutical-logistics process the very last thing the GDP·UCI initiative wants to do is to duplicate unnecessarily existing projects, tread on toes or reinvent wheels. Instead it aims to identify, and partner productively with, the industry' leading independent GDP authorities, best practice organisations and reform agencies (see Page 32 facing)

15. GDP Representation

As an independent and central body, the GDP·UCI is in a key position to Improve the status and prestige of GDP both as a quality function and as a job/career. The low self-esteem of some of the people working in GDP-related positions has already been mentioned (See Point 5. Page 24) and the GDP-ICU has a role to play as a mouthpiece for :

- encouraging strong leadership in championing the importance of a structured, collaborative, common-sense approach to good distribution practice in the pharmaceutical supply chain.
- driving an increase in competence thereby promoting sensible and proportionate risk management.
- reinforcing the status of both GDP as a discipline and as a career destination.
- promoting the wider appreciation and support of GDP within QA departments, boardrooms and the industry at large.
- maintaining a continuous working dialogue with the industry, legislators, QUANGO/NGOs etc. to further the interests of the program and its participants, and to take into account wider issues, drivers and opportunities that may impact the program.

16. Standards

Competitive technical development is a cardinal mainstay of a thriving modern economy and standardisation brings clarity, consistency and predictability to the innovation process. However, competing technical standards, by definition are less welcome since they are associated with uncertainty, confusion and unnecessary cost.

Conformity to universal standards helps reassure patients, customers and regulators that products are safe, efficient and good for the environment. The GDP·UCI has an aim of identifying and championing those technical and procedural standards that bring meaningful cost savings, efficiency gains and market access benefits.

For details concerning the relative prioritisation and sequencing of the above goals see Section 8, Page 44.

SUPPLY CHAIN TEAMWORK

On the basis of not wishing to duplicate or re-invent any existing wheels, the GDP·UCI has the objective of involving, and/or aligning with, other industry bodies and best-practice initiatives having similar aims and ambitions.

There are several organisations around the world that are involved in creating and distributing guidance on good distribution practice and related quality matters. Some of these are official bodies, others are industry non-profits or membership associations. All have amongst their goals that of raising quality standards in relation to the distribution of medicines.

For example:

- **United Nations (UN) System & African Union - WHO, PAHO, UNICEF, WFP, African CDC etc.**
- **PIC/S (Pharmaceutical Inspection Co-operation Scheme)**
- **Parenteral Drug Association (PDA)**
- **United States Pharmacopeia (USP)**
- **International Council for Harmonisation (ICH)**
- **National and supranational competent / regulatory bodies (human/ veterinary).**
- **Health & Humanitarian Bodies including public-private organisations, philanthropic institutions - GAVI, Gates Foundation, MSF etc**
- **PQG (Pharmaceutical Quality Group - division of Chartered Quality Institute).**

There are many other bodies, umbrella organisations and professional associations that are involved in the pharma-logistics supply chain, although not necessarily in a directly quality- or GDP-related capacity. Some of them represent vital links in the distribution process and are GDP-regulated by statute (e.g. authorised wholesalers) and these stand to benefit most from participating in a consensus-driven reform initiative such as GDP·UCI.

Organisations such as:
BSMA (Bio-Supply Management Alliance)
GIRP (European Healthcare Distribution Association)
IFPW (International Federation of Pharmaceutical Wholesalers)
ISPE (International Society for Pharmaceutical Engineering)
HDA (Healthcare Distribution Alliance)
RX-360 (international Pharmaceutical Supply Chain Consortium)

Other organisations and programs exist which have a primary objective of raising GDP standards, such as the IATA CEIV pharmaceutical air-freight certification program and the (much newer) sea-freight equivalent from the Port of Antwerp-Zeebrugge. The potential for collaborating with these will be explored.

Finally, all such partnerships will need to take into account any vested-interest conflicts and commercial incompatibilities. And there is also the potential issue of dealing with territorial protectionism where entrenched bodies or incumbent individuals take exception at what they misguidedly perceive as a competitive encroachment into their 'private' domains.

"Better regulatory compliance leads to improved standards that in turn improve patient safety and clinical outcomes"[3]

7. program scope & design

The scope of the GDP·UCI project is necessarily broad simply because the different aspects of GDP are all inter-related and any attempt at compliance reform needs to take into account the knock-on effects of any changes introduced. It is also important that it reflects, and is flexible enough to take into account of, important trends in the market such as the sustainability imperative or the increasing convergence of medicines and medical devices into hybrid treatments.

The role of technology in GDP·UCI

A very important GDP·UCI design principle relates to the role of technology. It is vital that the GDP·UCI utilises, and keeps under review, the latest technologies in its endeavours. Secure data sharing, product serialisation/traceability, real-time monitoring/visibility, compliance audit trails, inventory management, predictive analytics/ interventions are just some of the supply chain weaknesses that are being revolutionised by technologies such as artificial intelligence (AI), machine learning (ML), smart devices (IOT), robotics and automation, and cloud storage/distributed ledger.

It is interesting to note, nonetheless, that research indicates[2] that nearly three quarters of both shippers and LSPs are using manual, or substantially manual, reporting systems for GDP (See Fig 4). This not only speaks volumes about the Byzantine nature of GDP compliance but also, perhaps, the status of GDP in the current managerial hierarchy.

Another reason for this technical inertia is due to the difficulty in appraising and selecting technologies and technological platforms when there is so much at stake. Some 'technical breakthroughs' are little more than 'solutions looking for problems' while others inhabit a highly competitive landscape where the overall direction of technological travel and the destination is unclear. As a result this can mean that many companies are adopting a 'wait-and-see' strategy, unsure of which technologies will prevail.

Prevalence of Manual GDP Reporting Systems

Does your company currently operate a manual, or mostly manual, GDP reporting system?

Despite the vital importance of Good Distribution Practice, a majority of both shippers and LSPs operate simple manual reporting systems for GDP! In fact 73% of shippers are operating manual or substantially manual GDP reporting systems.

It is clear that there is a need for greater priority to be accorded to the GDP function both within PQS systems, QA departments, and amongst senior management.

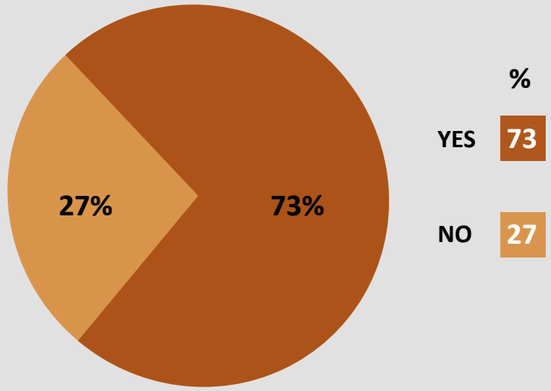


Fig.4

It is important to appreciate, therefore, that technology is being treated as a servant of the GDP·UCI program and not the other way round. Accordingly, each of the GDP·UCI program's core areas of activity, arranged in Primary Work Groups (PWG_- see Section 9, Page 48), needs to have access to expert advice and input on those areas of technology that are relevant.

For this reason the GDP·UCI structure includes a matrix of Special Interest Groups (SIG) containing subject-matter experts in a range of specialist fields that provide support and assistance on technical matters to the PWGs. This ensures that the solutions that are developed are applicable to current conditions and take into account the evolution of technology.

UNIQUE SELLING PROPOSITION (USP) FOR GDP·UCI

As can be seen from Section 6, Mission & Goals, on Page 28, the GDP·UCI has brought its many features together to create an unassailable USP from a user perspective. Its most unique hallmark, however, is representation of all the different stakeholders in the pharmaceutical distribution process. As a result the GDP·UCI program is very different from any other GDP-related system that exists or has been mooted.

Although many of the constituent parts of GDP·UCI, such as GDP training and certification, are available from other organisations, sometimes these are of questionable quality and they are often operated, or sponsored by sectarian interests. Unlike GDP·UCI, none of these other GDP-related initiatives has the aim of providing a fully integrated compliance system.

The following operational elements are core to the GDP ICU concept. Note that it will take time, resource and endeavour to commence on all these fronts and the reader is referred to Section 8, Priorities & Timeline, on Page 46 for the immediate areas of priority.

1. GDP STANDARDISATION

Most experts are of the opinion that the goal of creating new, binding, *de jure* standard(s) for GDP is unnecessary and, in any case, not a role for GDP·UCI. This is the task of regulators and standards bodies.

What GDP·UCI is doing is providing a more standardised approach to the process of GDP compliance. This is being achieved by providing actors with the ways and means of meeting current and future regulations. This includes the development of a range of GDP solutions based on 'compliance-certified solutions' (see pages 35 & 36). The more that can be done in this way to normalise the equipment and processes concerned the easier it will be to meet and exceed the GDP regulations (bearing in mind the regulations are the 'minimum acceptable' standards)

Of course, not every GDP process can be standardised, just as not every shipped item can be accommodated into a standard shipping container, but the current pharmaceutical freight system of developing and employing countless bespoke solutions to essentially meet the same, or equivalent, regulations is not only illogical but unsustainable.

COMPLIANCE CERTIFIED SOLUTIONS (CCS) FOR PHARMACEUTICAL GDP

'Compliance Certified Solutions' are seen as a means of demonstrating compliance with GDP regulations / guidelines using prescriptive solutions.

For example, a CCS for a given pharma logistics requirement and risk-profile would take the form of an integrated logistical system (including equipment, process, SOPs, risk management/ monitoring and environmental) which, if implemented and documented in exact accordance with the specification, would be deemed in conformity with regulatory performance requirements without further evidential justification.

In other words CCS is an 'accepted once, accepted everywhere' approach to regulatory compliance employing tried, tested and accepted practices to provide "how to" solutions within defined parameters.

CCS's have the advantage of being much more flexible than technical standards and can be tied to to an independent GDP-certification scheme. Their widespread adoption can provide certainty and scale economies leading to a better control of GDP compliance costs, the vagueness of which are a major barrier to improving GDP.

In a similar manner to technical standards, the scope of CCS's can be narrow/ technical or broad/ procedural depending on goals and needs. However, to avoiding the procedural minefield that a plethora of product-level CCS's would create, the GDP·UCI CCS's would relate only to full door-to-door services for each of the main freight modes. This is in accordance with the GDP·UCI goal of GDP simplification.

The determination and development of modal CCS will require expert judgement and control but their creation will be much faster and more flexible than then development of equivalent national or international norms.

This flexibility of the CSS approach means that CSS variants can be developed, not only for different transport modes, but for different national/ regional operating conditions and different risk profiles and these alternatives can be harmonised/ aligned for mutual cross-border recognition.

The important thing to understand is that each CCS needs to be independently defined, tested, and certified. The approval/acceptance of the regulators will then be sought. Such an industry-regulator partnership ensures the uptake of the concept and brings benefits to both sides in terms of financial savings and simplification of the entire assessment/approval process.

On the downside, one of the negatives of the CCS approach compared to a technical standards approach is that the former does not form a basis for easy comparison or benchmarking.

Finally, it is possible that the extant Poseidon pharmaceutical ocean freight model could provide the genesis for some of the first CCS solutions.

The Compliance-Certified Solution (CCS) Model

GDP regulations tell you what you have to do but not how you have to do it. They are non-prescriptive performance requirements that need to be translated into tangible, workable solutions.

Pharmaceuticals is not the only industry that is highly regulated and operating under severe scheduling and timing constraints. In complex sectors such as large-scale construction, concepts such as 'deemed-to-comply' 'DtC' prescriptive solutions have been developed as a means of streamlining and accelerating regulatory compliance without compromising standards or introducing unnecessary risk.

The GDP·UCI will develop an equivalent system specific to pharmaceutical GDP circumstances which will offer the same benefits whilst making GDP compliance more accessible, achievable and intelligible.

The GDP·UCI model will be based around "Compliance Certified Solutions" (CCS) which will be complete end-to-end logistical solutions that have been independently assessed to be in accordance with GDP requirements. Note that CCS - approval will NOT apply to specific supply chain actors or individual components. It will pertain to a complete logistics chains where all members are in full conformance with a prescribed CCS system mandated by the commissioning MAH or WDA-holding distributor.

A CCS for a given risk profile will prescribe a standard logistical procedure (including process, SOPs, risk management, and monitoring) which, if implemented in full accordance with the CCS specification, is regarded as meeting the required regulatory performance requirements. In other words it is a "how to" methodology using tried. tested and accepted practices that demonstrate GDP compliance.

CCS solutions are not narrow technical standards which means that different CCS solutions can be created for different risk scenarios such as climatic zones, infrastructure dissimilarities, local regulations etc.

Ultimately, CCS solutions will achieve full legitimacy when they are officially accepted by the regulatory authorities as meeting both the letter and spirit of the GDP guidelines.

Note that such CCS solutions will be a compliance option only. All other methods of compliance will continue to be valid so long as they fulfil regulatory requirements.

2. GDP HARMONISATION

The global harmonisation of practices, standards and regulations has long been recognised as a means of universally improving safety, raising quality, promoting competition, stimulating innovation, ensuring consistency and compatibility and removing barriers to trade.

However we need to be clear that although a related concept, harmonisation is not the same as standardisation. Standardisation is about absolute technical conformity while harmonisation is about the mutual alignment of disparate processes and procedures so that they offer equivalence in use or operation. In other words harmonisation is a process of mutual recognition through the establishment of recognised boundaries within which all activity must occur. Standardisation, on the other hand, is the creation of absolutely identical criteria from which no deviation is permitted.

For GDP we need both technical standardisation and procedural/operational harmonisation. At the same time, sufficient flexibility must be maintained to account for local conditions that may result in differences in what is operationally possible. For example, when the distribution infrastructure is fragile, or in extreme climatic conditions, where practices have to be adapted in a risk-assessed, justified manner at the discretion of the responsible person for GDP.

And it is important to understand that the GDP·UCI model will be working from the bottom-up, to ensure that all the assessment, certification, training and other elements are harmonised at an operational level to really drive efficiencies and quality improvements.

The need for harmonisation can be seen from the fact that regulatory complexity was specifically cited as a major impediment to the consistent and rigorous adherence to GDP by an overwhelming majority of shippers and forwarders in a recent poll.[14]

SHARED GDP AUDITS

The disruption and cost relating to multiple customer audits is something well-known to pharma logistics providers, especially those LSPs that are working with more than one pharma client. In such cases the imposed audit burdens are compounded since the audit criteria, thoroughness and format very often vary widely from client-to-client. Similarly, the periodic re-audits of existing suppliers is a perennial imposition and expense for both the shipper principal and its repeatedly audited suppliers.

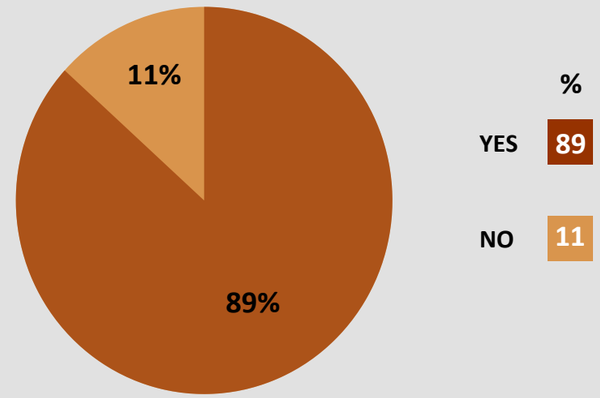
No surprise then, that the GDP sector is strongly in favour of an industry-wide shared audit program which would promote universal audit standards and allow pharma manufacturers and wholesalers (shippers) to mutually recognise results and thereby reduce audit frequency and inconsistency.

In fact a huge 89% of shippers and LSPs would welcome the introduction of a shared audit program with the figure rising to 94% amongst LSPs only.

Fig. 5

Would you find value in an industry-wide shared GDP audit compliance program?

Such a scheme would promote universal audit standards and allow pharmaceutical manufacturers and distributors to mutually recognise results and thereby reduce audit fatigue and inspection inconsistencies.



GDP practitioners in both the pharma and logistics sectors are overwhelmingly in favour of being part of an industry-wide shared audit program and see significant benefit for the systematic management and improvement of GDP.

3. SHARED GDP AUDIT SCHEME

A central part of the vendor qualification process is the quality audit. Whilst being absolutely necessary, supply chain qualification audits and shipper self-audits are invariably costly, disruptive and burdensome.

One of the basic GDP·UCI propositions rests in the concept of 'shared audits' in which, for example, pharmaceutical companies agree to mutually accept standard supplier audits and where the audit results are held in a secure, independent repository.

This mutual recognition will assure compliance while eliminating a massive amount of cost, work, disruption, duplication and unnecessary complexity. It will also provide a common platform for continuous improvement and industry benchmarking.

Note also that the GDP Compliance-Certified Solutions (CCS) scheme (see Page 36) would also benefit from audits that are available on a communal basis.

Interestingly, a full 89% of shippers and LSPs have said that they are firmly in favour of an industry-wide communal audit program (See Fig 5.) Another illuminating fact is that nearly two-thirds of pharmaceutical shippers rely solely on their contracted logistics provider) to qualify and audit their arms-length logistics suppliers (See Fig 6.)

A GDP·UCI system for sharing audit results will, of course, need very careful design with regard to data management and security. It will also require a pool of independent GDP auditors with the necessary training, competency and capacity to generate GDP audit reports with consistency and rigour.

4. UNIVERSAL GDP COMPLIANCE CERTIFICATION

Certification, although rarely an express regulatory requirement, can be a very effective means of raising standards and achieving uniformity of performance if done correctly. However, given the well-documented problems relating to third-party GDP certificates (see Box on page 40) there is no doubt that only a consensus-based system of universal GDP validation can ensure that certification delivers its promise.

As can be seen in Fig 7, the requirement for formal third-party GDP certification is a common requirement for Tier 1 forwarders and other LSPs providing transport and transport-related services within the pharmaceutical sector.

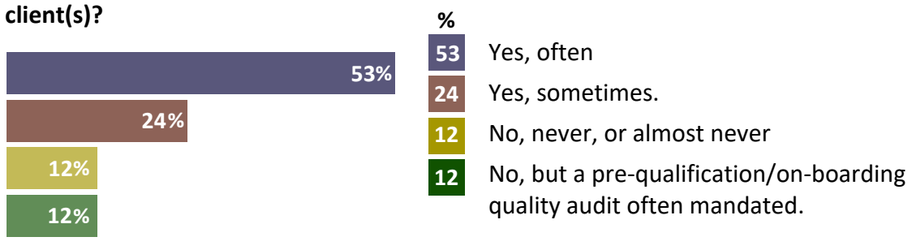
The absence of a universal, industry-recognised, qualification or certification that a logistics provider can achieve is seen by many as a major weakness in the current system and perpetuates the piecemeal, unsystematic approach we have today. The liability for product quality from creation to consumption generally rests with WDA and MAH holders who cannot simply wash their hands by abrogating responsibility along the supply chain. Ultimately the accountability for product safety rests with these parties. In the US the need to strengthen the GDP performance of the pharmaceutical supply chain is being addressed by the proposed revisions to FDA 21 CFR Part 205 by the US Food and Drug Administration calling for the introduction of federally-mandated National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers.[10]

A LSP registration and certification scheme could be based on the requirements for this and start out as a voluntary certificate. If successfully implemented, it could be proposed as an extension to existing ex-US GDP guidance.

Fig. 7

Requirement to hold GDP Certification as an LSP

If you are a logistics service provider, are you required to achieve/hold a GDP certification in the pre-qualification/on-boarding process with your pharma client(s)?



SUPPLIER AUDITS

Outsourced Supplier / Supply Chain Approval / Qualification

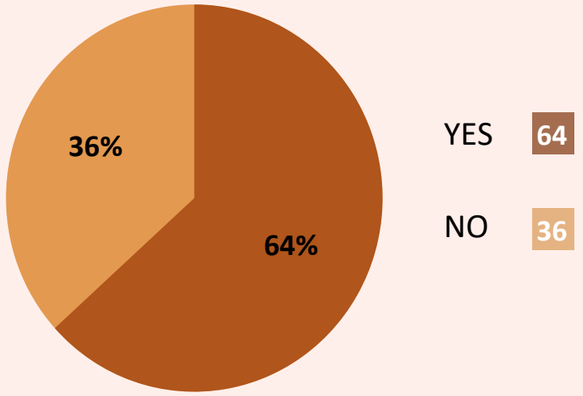
Pharmaceutical manufacturers are well aware that their distribution chains are made up of numerous partner organisations that are each vital to the lowering of costs, the driving of innovation, the maintenance of quality and, of course, compliance with the all-important GDP. And yet two thirds of pharmaceutical shippers rely on their immediate 3PL partners to undertake qualification and audits of upstream contractors and suppliers.

In view of the legal and inherited quality implications of this it is clear that the cost and effort of exercising tighter control over arms-length suppliers is deemed to over-ride the risks.

This finding clearly points to a need for a more consistent and efficient, cost-effective mechanism for selecting, assessing and monitoring upstream and downstream pharmaceutical supply chain partners.

Fig. 6

Does your supply chain qualification strategy rely on your directly contracted logistics partner (e.g. 3PL) to undertake up/downstream supplier audits/qualifications?



CERTIFICATION IS NOT ENOUGH

Certification schemes have an important role to play in raising GDP standards. But it is fair to say many certification schemes are far from perfect and are delivering questionable results. In fact, industry is littered with failed and poor certification schemes The Red Tractor scheme in the UK food sector, the global FSC scheme in the forestry industry, the RSPO palm oil scheme, the Kimberley certification scheme in the diamond trade and even IATA's CEIV pharma certification program have all attracted criticism recently.

Such schemes can be questionable because they can instil a false sense of security, they frequently encourage 'workarounds' and 'window-dressing' and they are often associated with high conformance costs. Most importantly, they are sometimes ridden with conflicts of interest. So although certification can be useful and necessary, it does have its limitations. Perhaps we are coming up against the inherent limitations of certification schemes?

New GDP·UCI Certification model

The requirement for the industry to comply with GDP creates a regulatory-driven need for pharmaceutical manufacturers and marketers to specify and control the supply chain competence of their outsourced supply chains. So the goal for GDP·UCI here is to create a high-transparency GDP assessment scheme that is industry recognised at both a national and international level, and which leads to an industry-recognised GDP certification. The scheme will be based on peer-to-peer alignment rather than master-servant relationships and will bring the simplicity, consistency and efficiency that is almost completely lacking at present.

This GDP·UCI certification model will not be based on simple pass/fail criteria which are unable to reflect the nuances of GDP activities nor provide an industry benchmark for comparison and continuous improvement purposes.

It is proposed that GDP·UCI certification take the form of either a "GDP score"or a categorised GDP rating/maturity ranking. So in the former case a company might achieve a 'score' of, say 85 while in the latter case the company might be categorised, for example, as "Gold"or "Band 2". Such a universal compliance scheme could be modular in design and embrace:

- SOPs
- Risk management
- Standards adherence
- Product/process/system qualification
- Supply-Chain/Shipping-Lane Compliance Assessment

and have modules specific to:

- Shippers/consignees
- Carriers - lines, overland
- Terminal Operators
- LSPs –forwarders, distributors etc.
- Suppliers

Certification of Compliance-Certified Solutions (CCS)

A separate certification scheme will be developed as an integral part of the GDP·UCI CCS mechanism (See pp 36-37).

5. APPROVED GDP TRAINING COURSES

GDP training and education at enterprise, managerial, operational, and individual levels will be a fundamental part of the GDP·UCI program.

GDP is only as good as its practitioners and its advocates and for this reason professional education, training and development underpin the entire GDP·UCI program. The standard of GDP·UCI training, its curriculum and its availability must reflect the quality and accessibility ambitions of the GDP·UCI program It must uphold its goals and values and enable its realisation.

In terms of depth and breadth some good GDP courses have been developed in the industry but standards vary, there are no harmonised curriculums/qualifications and good courses can be difficult to find.

As an often disjointed support exercise, systematic GDP training needs to be brought more into the realm of a co-ordinated approach to compliance. As a joined-up program, the GDP·UCI needs to find a way to link proof-of-training with the regulatory approval process; it needs to accommodate regional training needs/maturity while maintaining a harmonised approach; it needs to cater for all modes of transport, and it must have delivery platforms that reflect different working patterns and budgets.

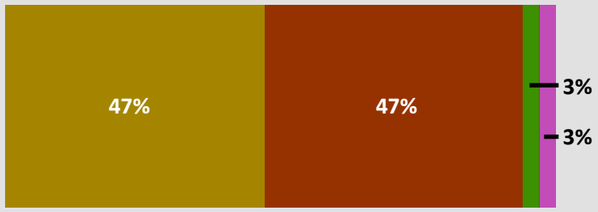
The GDP·UCI program will seek to work closely with established training organizations and specialists to develop the necessary agenda, content, and formats for differing regions and markets.

The GDP·UCI program will endeavour to address perceived shortfalls in the provision of satisfactory independent GDP training (See Fig 8.) and the fact that GDP training support is not often afforded by pharmaceutical principals to their key logistics partners (See Fig 9.)

Fig. 8

SOURCES OF GDP TRAINING SUPPORT

What is the principal source of your company's GDP training?



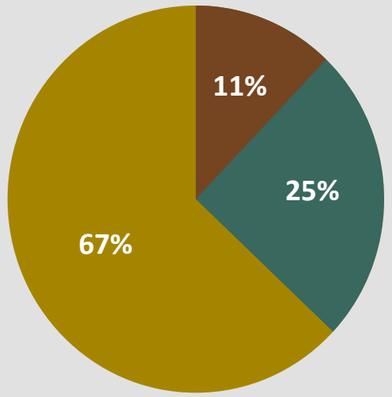
%	
47	We rely almost completely on in-house expertise/training for our GDP needs.
47	We use a combination of internal and external GDP training resources.
3	We almost completely rely on external training using third-party functional specialists/training professionals.
3	We wholly, or mainly, rely on appropriate GDP training being provided by our pharma clients.

The need for close affinity between pharma shippers and their front-line logistics providers goes without saying especially in view of the implications of poor GDP compliance yet 78% of LSPs do not receive meaningful GDP training/educational support from their pharmaceutical clients.

Fig. 9

SHIPPER TRAINING SUPPORT FOR LSPs

If you are a logistics service provider, do your pharmaceutical manufacturer or distributor clients provide you with meaningful GDP training/educational support?



%	
67	No, our clients make clear their GDP training expectations but provide little or no direct materials or tangible support.
25	Yes, our pharma clients are very interactive and work closely with us in addressing the GDP training and educational needs of our workforce and supply chain.
11	At the moment formal GDP training for our staff is not something that is forcefully demanded by our pharma clients and as a result we give it minimal attention.

As an often disjointed support exercise, systematic GDP training needs to be brought more into the orbit of a co-ordinated approach to compliance.

GDP·UCI Training Program Fundamentals

- A structured and modular training programme offered in a range of delivery models covering the end-to-end freight process
- Aimed at all actors in the supply chain for pharmaceutical logistics with initial focus on the pharmaceutical manufactures and distributors responsible for shipping
- Geographical coverage: global
- Multi-modal in scope including the training needs for co-loaded and inter-modal shipping
- In addition to supply chain management education, the industry needs operational guidance including:SOP-specific training
- Quality and risk - application of quality risk management (QRM) in GDP
- GDP - regulatory compliance, international standards and best practice.
- Personnel - RPs, roles and responsibilities
- Premises - environment/temperature control, dock handling, consignment preparation, conditioning, stuffing, loading etc.
- Co-loading - consolidation/de-consolidation best practice
- Documentation and data integrity
- Operations - storage; outsourcing; recalls; reverse logistics etc.
- Internal audits
- Equipment and systems - containers, labelling, protection, packaging, conditioning, monitoring, tracking - qualification/validation, change control etc.
- Waste and sustainability

6. GDP KNOWLEDGE BANK

A centralised 'GDP Knowledge Base' designed to be used by GDP practitioners would be a useful means of providing improved consistency in interpretation and application of regulatory requirements.

It is envisaged that such a one-stop-shop knowledge transfer network could be maintained by the Consultation Cluster on a "wiki-style"community editing basis.

7. STANDARD FORMS OF CONTRACT FOR LSP OUTSOURCE INCL. QTAs

The GDP·UCI will investigate the scope for using standard forms of contract for outsourced distribution purposes including vital quality-technical agreements.

The relationship between the various parties in the distribution supply chain is ultimately governed by the legally-binding agreements that are in force. Poor contracts and contractual ambiguity are matters that can impede the correct adherence to GDP regulations and, in a worst-case scenario can contribute to contractual defaults and/or expensive litigation.

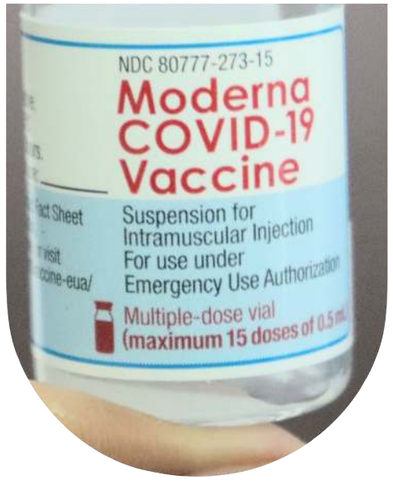
Not only do standard form contracts codify acceptable standards of performance, they bring uniformity, consistency and a clear understanding of the rights, duties and obligations of each party. Crucially, they reduce the time, effort and transaction costs for all parties and have been shown to actively encourage trade.

Standard contracts allow companies to focus on project outcomes rather than the terms of engagement thus contributing to an enhanced degree of risk management. Furthermore, over time, standard form contracts establish a body of case laws that can be referred by parties in case of disagreement over any issues. This benefits the whole industry.

"Global organisations can, and should, only have one set of GDP standards."[3]

8. priorities & timeline

The inter-related nature of all the different facets of GDP means that the GDP·UCI program is necessarily broad in scope in order to encompass all aspects of GDP compliance at management and operational levels.



This makes GDP·UCI a major exercise and it is important that the program is developed in a structured yet phased manner with a clear emphasis in the first instance on those areas that have either been identified as critical pain-points or are *sine qua non* to the project's success. The GDP·UCI program will also endeavour to secure some 'quick wins' to gain attention and to demonstrate the potential for tangible reform.

Even with a controlled step-by-step approach the success of the GDP·UCI project will be contingent on the continuous and unstinting input and support of the program network. And, as mentioned on Page 32, it will be seeking to partner with those independent bodies and institutions already operating in this field that are willing and able to add positive value.

Main priority areas for the first phases of the program.

1) Immediate Goals (Phase 1) Fig 10

- Draft and agree the GDP·UCI Framework of Rules & Regulations
- Enshrine the agreed project scope, structure, terms of reference and governance framework in the program Framework of Rules & Regulations (See Section 6, Mission & Goals, Page 28)
- Put in place the program roll-out schedule (See Facing Page)
- Agree the funding/commercial model and commence implementation (See Section 13, Funding, Page 64)
- Design and put into operation an on-line collaboration platform (See Section 10 Network Management, Page 58)
- Institute a Market Engagement Group with a first objective being the official launch of the GDP·UCI project in February 2023

2) Short-term Goals (Phase 2) Fig 11

- Establish work-groups, formulate detailed strategy/ activity plan and commence development for:
  - Guidance / Solutions incl. standardisation/ harmonisation/CCS (See Section 7, Program Scope, Page 34)
  - GDP certification program. (Audit/Certification PWG) (See Section 7, Program Scope, Page 34)
  - Shared audit program incl. platform (Training/Education PWG) (See Section 7, Program Scope, Page 34)
- Create design, format and operating model for:
  - Accredited GDP-ICU training courses incl. partner organisations and course priorities (Training/ Education PWG) (See Section 7, Program Scope, Page 34)
  - GDP Knowledge Bank (Training/Education PWG) (See Section 7, Program Scope, Page 34)
  - Market Engagement program (See Section 12, Market Awareness & Engagement, Page 62)

3) Medium/Long-Term Goals (Phase 3)

- Launch approved CCS solutions
- Pilot GDP certification program
- Pilot Shared Audit Program
- Investigate the potential for Standard Contract Forms

4) Maturity Goals (Phase 4)

- be the global leader and authority in all matters GDP
- To be working in partnership with regulatory authorities to champion GDP compliance
- To be an official accreditation body for GDP conformity assessments
- To be making a major contribution to safer and more sustainable medicine distribution

Fig. 10

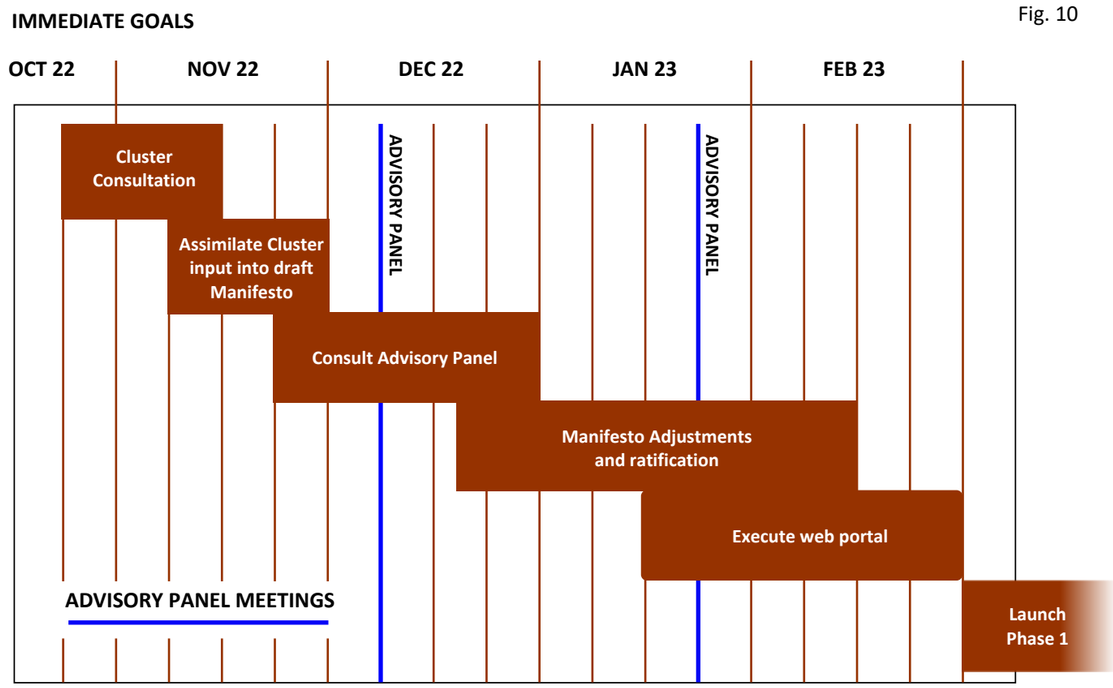
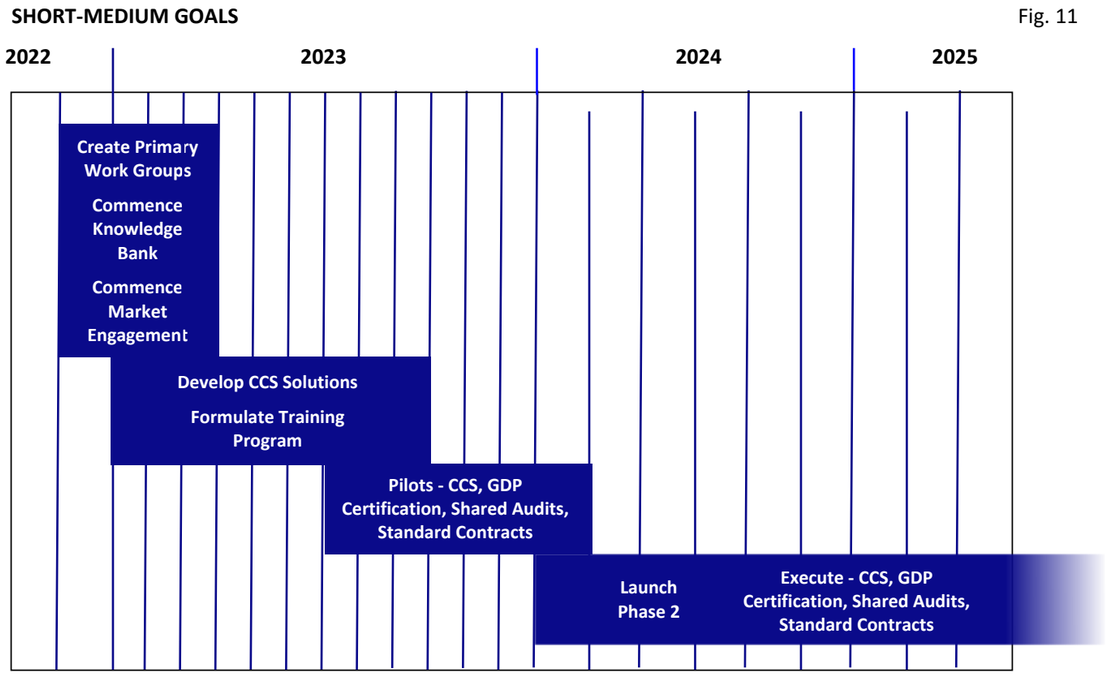
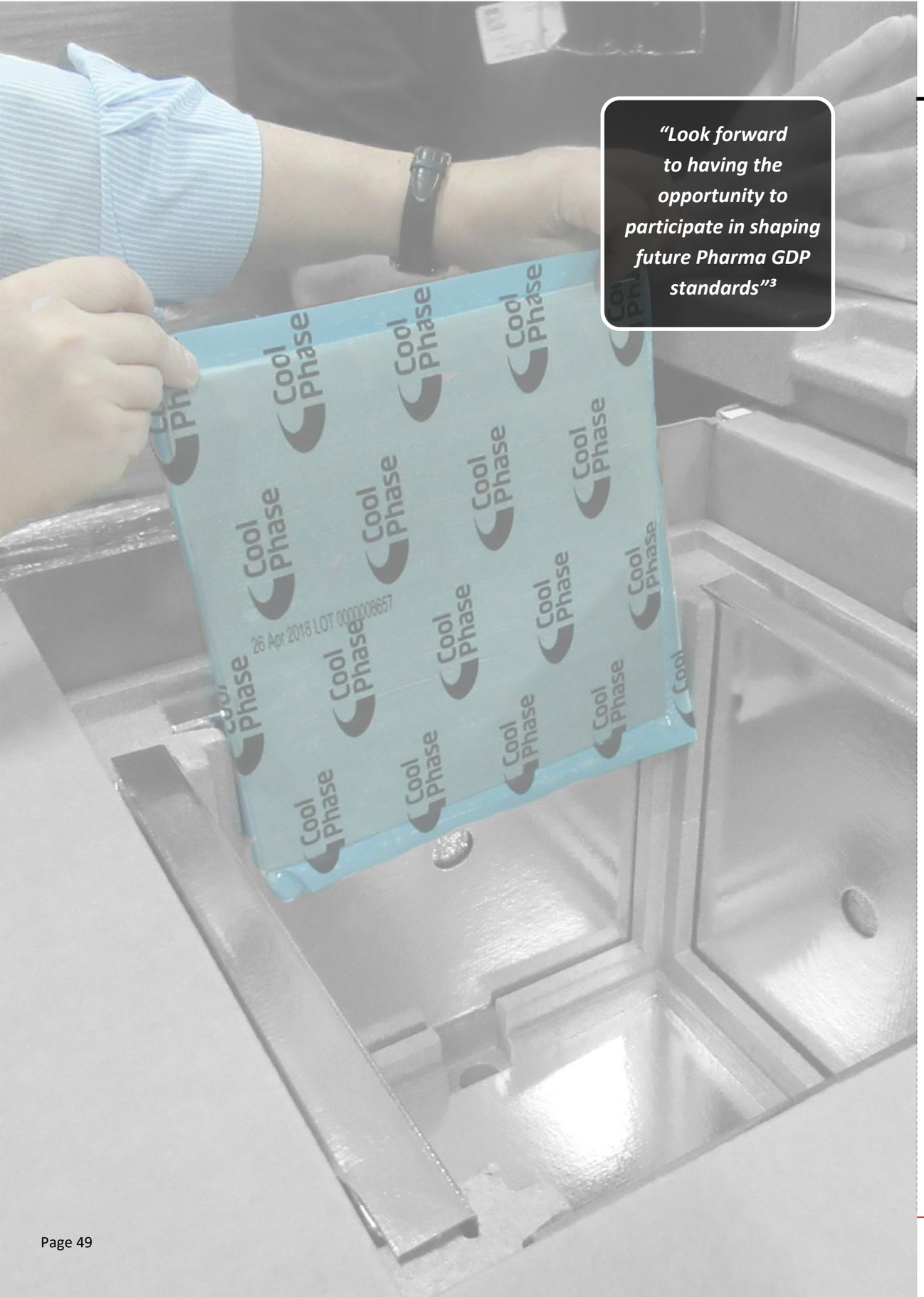


Fig. 11





"Look forward to having the opportunity to participate in shaping future Pharma GDP standards"[3]

9. structure

To enable GDP·UCI to function as a group and capture and share the inputs and outputs of the, at the time of writing, 230+ individual members of the GDP·UCI Cluster requires a systematic and unambiguous arrangement of people and resources.

One of the most compelling and unique characteristics of the GDP·UCI initiative is that it is a very 'broad church' allowing active consultation and engagement with all the GDP stakeholders in the pharmaceutical supply chain. Not only does it contain GDP and quality professionals, it has also attracted a sizeable array of experts in areas such as IT, sustainability, insurance, thermal packaging, transport modes - road, rail, sea, air etc. etc (See APPENDIX 3. Page 71)

The challenge has been how to physically structure the GDP·UCI project in order to deliver its goals efficiently and comprehensively by way of tapping into the enormous array of talent and expertise that the network represents. The network configuration needed to reflect the broad membership base, its collaborative disposition and its democratic structure.

Furthermore, the structure had to be simple, transparent and conducive to communication, interaction and goal achievement. And all GDP·UCI contributors and supporters needed to be given an identity and a purpose in return for freely devoting their time and expertise to this collective project.

Of course it is unrealistic and impractical to involve everyone all the time. The availability of individual as volunteers will differ greatly depending on individual circumstances at any moment in time. Some members will be highly supportive but physically unable to contribute, others will have very specialist areas of expertise that, although important, are only needed at certain junctures or in certain circumstances.

So it is vitally important to keep these subject-matter experts interested and involved because they will provide alternative perspectives and will no doubt be needed as the program develops.

In devising a suitable structure the following questions were considered:

- How will it ensure all supply chain factions are properly represented?
- In what way will it demonstrate that variables such as different company sizes, gender/ethnic representation etc. are being taken into account?
- Where can solution vendors fit in?
- How will it give voice to individual subject matter experts?
- How will it involve regional/national experts and ensure that local diversity/requirements are taken into full consideration?
- Where will it put industry bodies and trade associations that wish to be part of the GDP·UCI initiative as organisational members?
- Will it include media organisations that can assist in raising awareness of the GDP·UCI program?
- What happens when a new Cluster member joins? What engagement/progression options will they have if they are keen to contribute?
- How can it accommodate different, and changing, levels of individual commitment to GDP·UCI?
- How can the structure visibly demonstrate that GDP·UCI is a globally-focused initiative?

Based on the above considerations and taking into account the program objectives and priorities identified in Sections 6 and 7 and in consideration of the need to have a structure that facilitates the engagement and interplay of the entire network, the structure shown in Fig 12. below has been drawn up.

This uncomplicated arrangement addresses most of the issues above by the simple expedient of supporting the Primary Work Groups (PWGs) with a comprehensive array of Special Interest Groups (SIGs).

GDP-UCI GOVERNANCE COUNCIL

The Governance Council is the top tier in the GDP·UCI structural hierarchy (See Section 11 Page 60) and, as per the GDP·UCI Framework of Rules & Regulations, is responsible, inter alia, for high-level policy, strategic issues, adjudication and interpretation of the rules.

GDP-UCI ADVISORY BOARD

The current Advisory Board functions in accordance with its published Role Description (See Page 54).

The Advisory Board will also initially perform the role of GDP·UCI Governance Council (See Section 11, Governance, Page 60). The Advisory Board and Governance Council are expected to segregate into two discrete executives after completion of the first year of operation.

SPECIAL INTEREST GROUPS (SIG)

The SIGs will, in effect, be mini-knowledge-hubs containing subject matter experts and other interested parties arranged as a support matrix. The SIGs will act on an extempore basis providing ad-hoc assistance and advice to the Work Groups, as and when required.

In some cases they may be required to provide consensual replies to questions posed by the PWGs and in order to facilitate the necessary interactions for this to occur, each SIG will be provided with its own workspace on the GDP·UCI online collaboration platform (OCP) (See Section 10, Network Management, Page 58)

The compact PWGs cannot possibly include delegacy from all the different pharmaceutical markets around the world. Giving the PWGs direct access to regional-specific expertise within the SIG network will alleviate this problem.

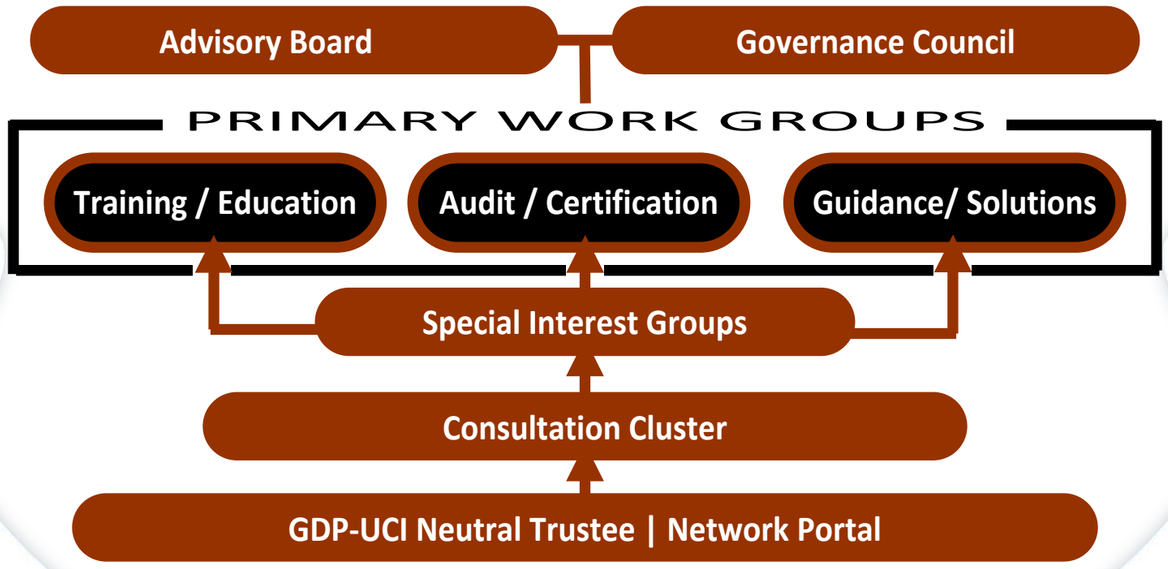


Fig. 12

There will be a protocol attached to SIG membership:

- The SIGs will represent all the main GDP stakeholder groups and geographical markets/regions.
- A SIG will be formed where there are four or more specialists in the same field. Where there is less than four then those concerned will be tagged as Subject Matter Experts (SME). There is no upward limit to the size of a SIG.
- Unlike the Focus Groups, the SIGs do not have a specific project brief, their role being one of providing ad-hoc support in the form of knowledge-and expertise to the PWGs and future technical committees.
- SIGs are informal cells. Other than as stated here, there are no prescribed rules, obligations or guidelines as to how each Special Interest Group (SIG) operates. It is expected that the SIG groupings will lead to meaningful dialogues and inputs to the program but they can be organised as formal or informal as their members' decree.
- The SIGs will house commercial solution. Note that, for reasons of commercial and technical objectivity, solution vendors are unable to participate directly in a PWG.
- Cluster members will be encouraged to join all the SIGs appropriate to their position. So, for example, someone working as a trainer for a ground handler at Changi airport could register in the Training, Air Transportation and SE Asia SIGs.
- It is GDP·UCI policy that no PWG can have more than one member from the same company. However, this restriction does not apply to the SIGs. A SIG can have multiple representatives from a single organisation if the latter so wishes. Similarly, an organisation can be represented on multiple SIGs by different people if it so desires.
- Since the Primary Work Groups are likely to mutate and diversify over time (e.g. by the establishment of technical committees and other working groups) and PWG members will retire and migrate, the nominees for additions and replacements will come from the SIG membership.
- Active SIG members will be granted “GDP·UCI Champion” status and be entitled to use the Champion Logo below on a personal or corporate basis.

CLUSTER ADVISORY BOARD ROLE DEFINITION

The establishment of the Advisory Board in support of the GDP Universal Compliance Initiative is a vital component of the project structure. This description has been prepared to provide a concise summary of the role and requirements of Advisory Board members.

2. CAB Role

The primary aim of the Advisory Board is one of providing scrutiny and focus to the individual GDP·UCI Primary Work Groups (PWG) and, if necessary, challenging their output and direction.

It serves as an informal and independent sounding board for ideas and strategic thinking in the form of a group of recognised experts in the fields of pharma GDP/logistics that is supportive of the vision, guiding principles, and goals of the GDP·UCI project.

To assist in the fulfilment of their respective briefs, the GDP·UCI PWGs will be encouraged to seek regular ‘wise counsel’ from the Advisory Board in the form of feedback, strategic guidance, unbiased insights and general advice

3. Advisory Board Composition

The Advisory Board will endeavour to be as representative of the GDP community as possible within the constraints of a volunteer body.

It is expected that the Advisory Board will number around 8 -12 GDP/Supply Chain experts including a representative from the the initiative’s Neutral Trustee (Team Poseidon Ltd). The Advisory Board can be seen in the GDP-ICU structural hierarchy on Pages 51-52.

The Advisory Board can, at their discretion and by mutual agreement, co-opt additional members, both temporary and permanently, in order to add expertise in key focus areas.

4. Appointment Basis

Membership of the Advisory Board is by invitation only. It is a voluntary, non-statutory and non-contractual role with all participation on a pro-bono basis.

5. Expected Time Commitment

The expected time commitment will be quarterly virtual meetings of approximately one-hour duration and attendance at one annual physical meeting of one or two days at a mutually convenient location.

Any other inputs will be ad-hoc and at the individual member’ personal discretion although it is expected that Advisory Board members will make themselves available on an occasional basis by telephone or e-mail to provide views, advice and guidance to the Focus Groups.

6. Tenure

Advisory Board members are appointed on a 3-year tenure renewable by mutual agreement.

7. Advisory Board Officers

The Advisory Board Chairman (and any other officers deemed necessary) will be appointed from within the Advisory Board by mutual agreement. In the absence of mutual agreement an equitable voting system will be devised and agreed. The Advisory Board Chair will rotate at annual intervals in a predetermined manner in order to capture diverse leadership strengths and avoid leadership stagnation.

8. Meetings and Communications

The Advisory Board will decide the frequency and format of all and any meetings to discuss Advisory Board matters (but see Item 5).

9. Dedicated Advisory Board Collaboration Tool

The Advisory Board will enjoy its own secure and private workspace in the GDP·UCI on-line Collaboration Platforml.

Initially the following SIGs have been established:

Operational & Functional SIGs:

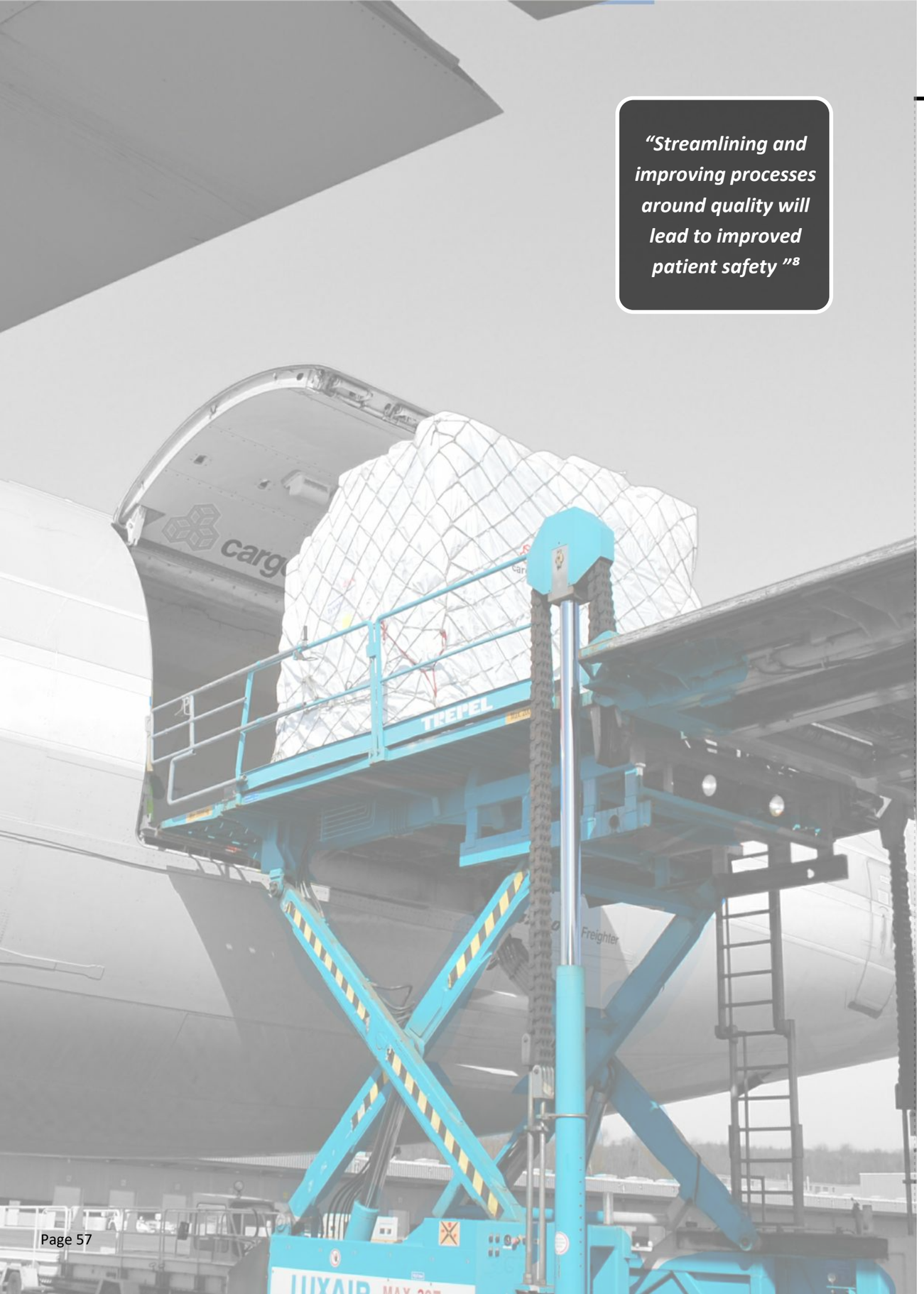
- Freight mode - Air, incl. carriers, infrastructure operators
- Freight mode - Water, incl. carriers, NVOCCs, infrastructure operators
- Freight mode - Road, incl. carriers, infrastructure operators
- Freight mode - Rail, incl. carriers, infrastructure operators
- Logistics Providers incl. forwarders / integrators/ handlers etc.
- Warehousing / inventory management incl. fulfilment centers/ reverse logistics
- Wholesalers / distributors / retailers
- Manufacturers incl. CMOs, CDMOs for medicines, vaccines, APIs, generics and excipients
- Clinical trials incl. CROs
- Veterinary manufacturers and all animal-related businesses
- Independent GDP practitioners / consultants
- Quality management incl QP, RP and other GDP QA professionals
- Health agencies and related organisations
- Regulatory
- Training
- Auditing
- Insurance

Geographical SIGS:

- Europe
- North America
- Indian Subcontinent
- SE Asia
- East Asia
- Africa
- Middle East
- South / Central America
- Other Regions

Specialist SIGs:

- Sustainability
- Packaging / containers
- Temperature management incl. data monitoring
- Marketing
- GDP Knowledge Bank
- IT / tech. innovations
- Serialisation / Track & Trace
- Humanitarian
- Partner organisations



"Streamlining and improving processes around quality will lead to improved patient safety "[8]

10. network management

Secure GDP·UCI Web Portal

Secure GDP·UCI Collaboration Platform

The efficient management of a large, diverse and geographically distributed network like the GDP-UCI requires a dedicated web-based portal This is the only practical means of efficient co-ordination and communication between multiple parties and disciplines and across multiple time zones. A central platform of this nature is also essential for affording the Governing Council a relevant overall perspective on the project to enable it to discharge its duties.

Built on a commercial, subscription-based data-sharing intranet, the GDP-UCI Collaboration Platform exhibits the following attributes and functionality:

- Security accredited
- Granular permissioning
- Workgroups
- Discussion boards and other tools
- Storage - files, message streams etc
- Calendars
- Project/task management & status reporting
- Document management incl. versioning
- Alerts/notifications
- Whiteboarding
- Accessible on multiple platforms incl. phone
- Ease of use/onboarding
- User support
- Surveys/polling capabilities
- Wide customisation options

All GDP-UCI subscribers are present on the Collaboration Platform and each Primary WorkGroup and Special Interest Group has its own dedicated workspace.

"There will be industry benefits from speaking with one voice about how risks are identified/ managed "[8]

11. governance

As an industry-wide initiative, the good and transparent governance of the GDP·UCI is vital to its credibility, its effectiveness and, ultimately, its survival.

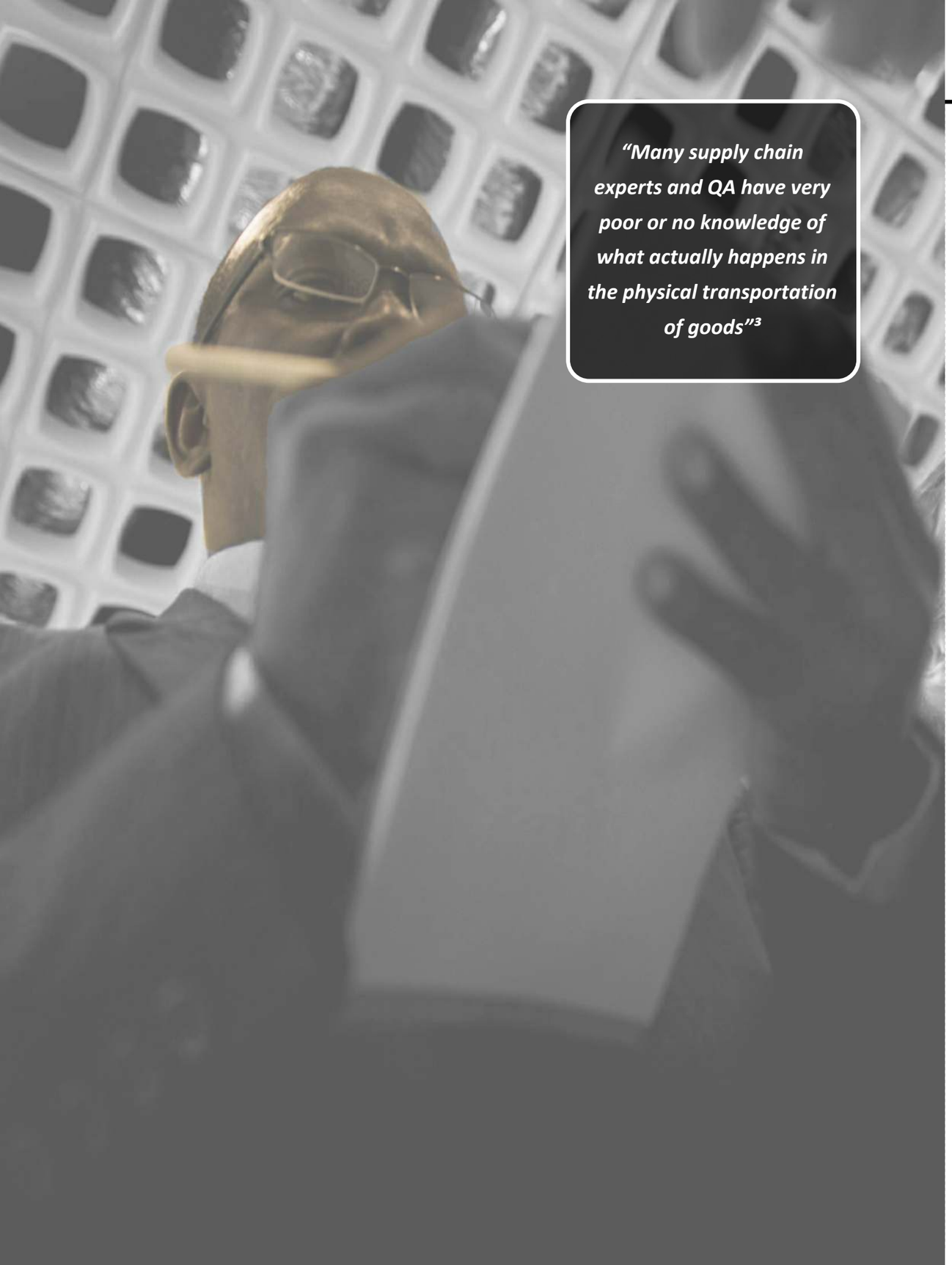
Being a network of independent GDP stakeholders means that GDP-ICU must be managed and directed according to democratic principles and with due consideration to the equitable application of common rules and policies amongst all its members.

The Governance Council is the top tier in the GDP·UCI hierarchy (See pp 49/50) as per the GDP·UCI Framework of Rules & Regulations and is responsible, inter alia, for high-level policy, strategic issues, adjudication and interpretation of the rules.

It is responsible for ensuring the means for democratic involvement of the network in matters of high importance and strategic direction.

At the outset the GDP-UCI Governance Council and the GDP-UCI Advisory Panel, although discrete entities, are be comprised of the same executive team (See Appendix 2 Page 70). Terms of Reference for the Council and its protocols are agreed and codified as part of the program's Framework of Rules and Regulations.

A Neutral Trustee, Team Poseidon Ltd, serves on the Governance Council providing a dedicated management function which, inter alia, administers the program, directs and controls the Primary Work Groups, oversees membership, encourages member activism, promotes the program at every opportunity and keeps it focused and on track.



"Many supply chain experts and QA have very poor or no knowledge of what actually happens in the physical transportation of goods"[3]

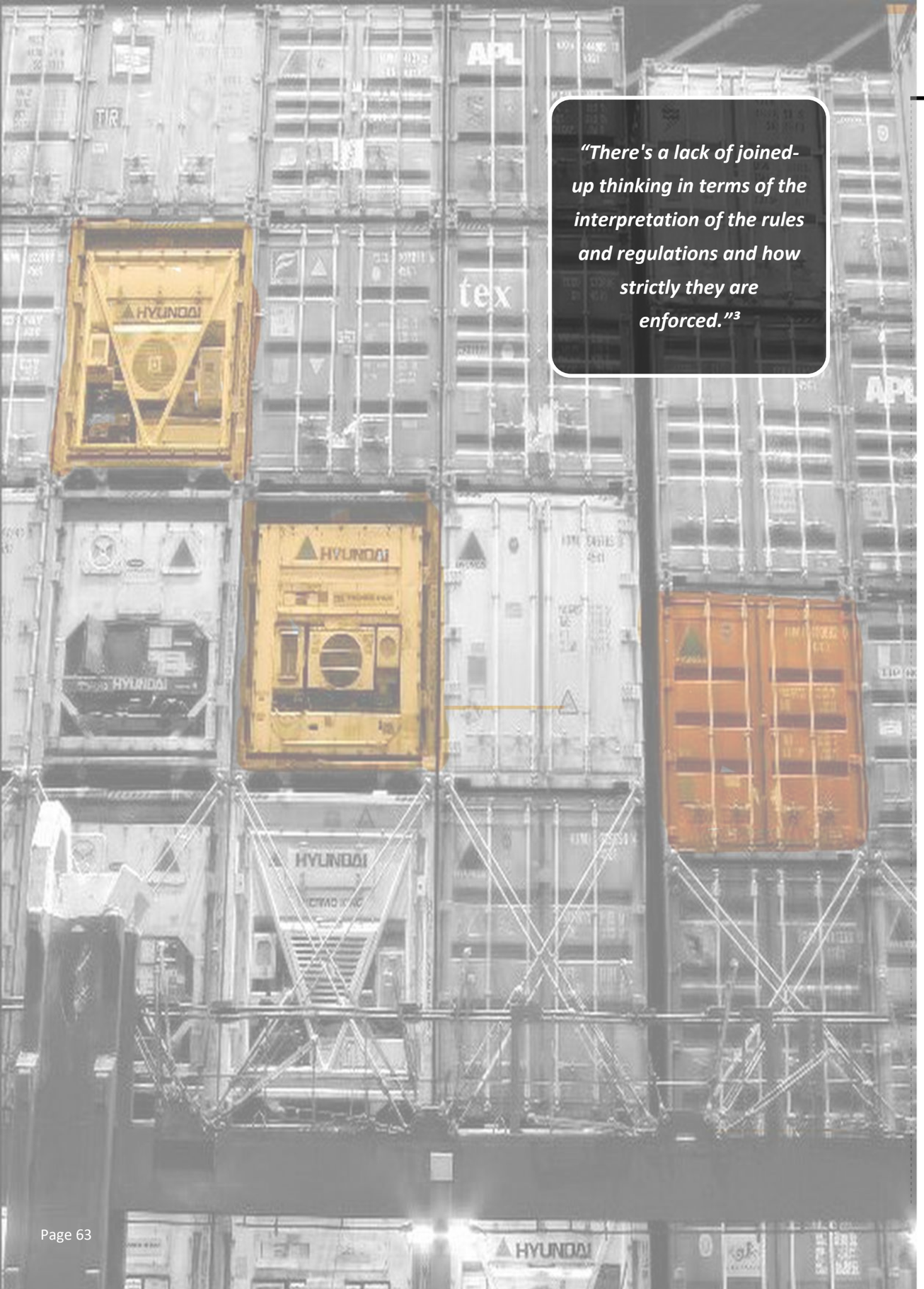
12. market awareness & engagement

The GDP·UCI is being promoted to the market through a structured engagement program in order to solicit support and input and, further down the line, to encourage adoption of the program outputs.

For this purpose a Marketing SIG is in place with the brief to push the program and its value proposition into all corners of the industry both structurally and geographically.

This SIG is expected to formulate and implement PR opportunities and devise thought leadership campaign to raise the profile of the initiative. Social media will play an important part in this.

During 2023 a GDP·UCI website will be developed as a window on the program to raise awareness and serve as a conduit for attracting new GDP·UCI subscribers.



“There's a lack of joined-up thinking in terms of the interpretation of the rules and regulations and how strictly they are enforced.”[3]

13. funding

Like any independent movement, in order to flourish and be sustainable the GDP·UCI needs to have a stable and continuing income. The costs of administering and maintaining a global project like this can be quite substantial. However, by sharing the financial burden and being creative it has been possible to conceive an income base for GDP-UCI which is scalable and provides a pathway to multiple revenue streams.

However, it is important to understand that many of the revenue sources for the project will only materialise significantly down-stream since they will be dependent on longer-term project outcomes such as the initiation of certification, audit platforms, training programmes etc. The fee structure and revenue mix that follows includes those items with a longer gestation period.

On agreement of the revenue generating program it will be expanded into an official GDP·UCI Financial Plan.

1. MEMBER SUBSCRIPTIONS

Membership of GDP·UCI is on a corporate basis with a tiered-subscription system based on company size and company type. Subscriptions have been set at a level to reflect the value derived, or attainable, from being a member of a given category. In particular the fee-scale has been designed to ensure that sole-traders, start-ups and micro-businesses are not deterred from joining since the RP, training, auditing and consultancy markets have many practitioners in these categories.

Payments are annually in advance and the Membership Term runs from March to February. A one-off Joining Fee is payable to offset onboarding costs and to encourage continuous membership. However, However, organisations that register for Membership prior to 1st March 2023 (GDP-UCI "Founder Members") and pay their full 2023-24 subscription fee prior to May 1st 2023 will qualify for exemption from the Joining Fee.

The 2023 membership fee matrix is shown in Fig 13, Page 67 and full subscription terms can be found in the "The GDP-UCI Membership Experience" document available on request.

Membership Tiers

- **Category 1:** Pharmaceutical Manufacturer incl. CMO
- **Category 2:** Dedicated CRO/CTO
- **Category 3:** Distributor / Wholesaler
- **Category 4:** Logistics Service Provider incl. carriers/hubs
- **Category 5:** Solution Provider incl. products, systems, services
- **Category 6:** GDP Service Company incl. training, auditing, consultancy
- **Category 7:** Affiliate Organisations incl. educational, institutional, associations

Organisation Size

- **Band A:** > $500m worldwide gross revenues
- **Band B:** $100m - $500m worldwide gross revenues
- **Band C:** $50m - $100m worldwide gross revenues
- **Band D:** $10m - $50m worldwide gross revenues
- **Band E:** $1m - $10m worldwide gross revenues
- **Band F:** <$1m worldwide gross revenues
- **Band G:** Sole traders with < $100K worldwide gross revenues

FOR SUBSCRIPTION FEE CONTEXT cf:

- Members of the PSCI (Pharmaceutical Supply Chain Initiative) pay $5,500 to $32,500 pa depending on turnover. (2022 rates)
- Members of the Rx-360 (International Pharma Supply Chain Consortium) pay $30,000 for pharmaceutical manufacturers, $12,000 for small pharmaceutical manufacturers and $6,000 for suppliers). (2016 rates)
- Members of the IFPW (International Federation of Pharmaceutical Wholesalers) pay $11,000 to $105,000 on a revenue-based sliding scale (2022 rates)

Organisation Definition

For membership purposes, organisations are defined as discrete operating units or organisational entities. So a large multinational or conglomerate organisation might be comprised of several, largely autonomous, operating entities or subsidiary companies each of which, if requiring GDP-UCI membership, would be required to join GDP-UCI in their own right. In cases of dispute or uncertainty regarding the membership tier/status of a member candidate the decision of the GDP-UCI Governing Council will be final.

2. SPONSORSHIPS

A number of sponsorship opportunities are available to GDP-ICU members which provide high profile brand awareness and the ability to promote the sponsor's product to decision-makers and policy makers.

Sponsorship opportunities include:

- Sponsorship of GDP·UCI Collaboration Platform
- Sponsorship of GDP·UCI newsletter
- Sponsorship of GDP·UCI webinars
- Sponsorship of GDP·UCI conference and other flagship events

Sponsorship will give the sponsor high visibility both within and outside the GDP·UCI network through the ability to merchandise the association in advertising / PR / social media etc. marketing campaigns.

3. COMMERCIAL GDP EVENTS

Different types of event, both real and virtual, will form the basis for a regular income stream. Regional GDP conferences and a series of informative webinars are planned.

It is a common viewpoint that many pharma trade shows and conferences are of low quality, are difficult to measure, fail to live up to the expectations and generally represent poor value for money. GDP-UCI has conducted a survey amongst the Cluster members to collect impressions and suggestions for an initial event in(mainland Europe for early 2024.

Discussions are underway with established conference producers to investigate a flagship GDP conference event that would provide a platform for GDP innovation, authority and reform.

Another potential revenue-generator is GDP-ICU hosted shared pavilions at major industry events. These would present a united front to the market while significantly curtailing costs for participants.

4. GDP WEB DIRECTORY

Finding the most GDP-adept supply-chain partners and the best sources of GDP-related services can be a very time-consuming and hit-and-miss process. The difficulties in finding and assessing the right suppliers means that many organisations end up with sub-optimal providers or, in some cases, are reluctantly forced to develop GDP resources in-house when it might be faster and more economic to contract out.

A definitive directory will help legitimise GDP-compliant and GDP-enlightened businesses and its reach will extend, via search engines and social media, far beyond the GDP-ICU Cluster. Subscribers will enjoy a choice of listing options, categories, linkages and profiling opportunities.

5. LICENSING ACTIVITIES

The licensing of GDP·UCI branded services is expected to be a major source of revenue in the longer term**.**

Licensed products will include:

- **Approval and certification of CCS solutions**
  CCS solutions will require to be fully tested and qualified at the end of which a fixed-validity certificate will be issued for which a fee will be payable.
- **Training licences**
  Approved GDP·UCI training courses will be licensed from GDP·UCI.
- **Audit licences**
  Approved GDP·UCI auditing services will be licensed from GDP·UCI.
- **GDP·UCI shared audits**
  An access fee or subscription will be charged for retrieval and use.

For comparison purposes the reported license fee for one shared RX-360 audit report ranges from $2,500 to $5,000 (USD).

ANNUAL SUBSCRIPTION MATRIX

Fig. 13

CAT	DESCRIPTION	BAND A > $500m WGR PORTAL SEATS[a] 25	BAND B $100m - $500m WGR PORTAL SEATS[a] 20	BAND C $50m - $100m WGR PORTAL SEATS[a] 10	BAND D $10m - $50m WGR PORTAL SEATS[a] 5	BAND E $1m - $10m WGR PORTAL SEATS[a] 3	BAND F <$1m WGR PORTAL SEATS[a] 2	BAND G Sole traders < $100K WGR PORTAL SEATS[a] 1	JOINING FEE[c]
1	Pharma Manufacturer Incl. CMO	6,900	5,750	4,600	3,450	2,300	1,150	N/A	500
2	Dedicated CRO / CTO	6,900	5,750	4,600	3,450	2,300	1,150	N/A	500
3	Distributor / Wholesaler	6,900	5,750	4,600	3,450	2,330	1,150	N/A	500
4	Logistics Service Provider incl. carriers & logistics hubs	6,900	5,750	4,600	3,450	2,330	1,150	N/A	500
5	Solution Provider incl. products, systems, services	9,200	5,750	4,600	3,450	2,330	1,150	N/A	500
6	GDP Service Company incl. training, auditing, consultancy	9,200	8,050	6,086	5,750	2,330	1,150	250	500 (250 for Band G[d])
7	Partner / Affiliate / Observer Organisation[b] e.g. educational, institutional, associations etc.	TBA	TBA	TBA	TBA	TBA	TBA	TBA	N/A

All figures $USD and exclude VAT where applicable.

WGR = worldwide global revenues.

[a]Portal seats equate to number of voting rights on member-reserved/assigned matters. Additional portal seats can be purchased at the Band G Cat 6 rate but with no voting rights attached.

[b]Reciprocal membership may be required.

[c]Organisations registered as full members before March 1st 2023 and with annual fee paid in full before 1st May 2023 will be excused the Joining Fee.

[d]50% discount for Band G sole-traders only.

APPENDIX 1

CITATIONS

[1] *The Challenge of Compliance in Life Sciences, Moving from Cost to Value; Deloitte 2015*

[2] *GDP Consultation Cluster Survey Report 2021/2022; Poseidon*

[3] *Unsolicited responses to GDP-ICU initiative announcement from Cluster members*

[4] *European Medicines Agency*

[5] *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ICH Q1A 2.1.7 (1)*

[6] *Centers for Disease Control and Prevention, Epidemiology and Prevention of Vaccine-Preventable Diseases; 13th Edition April, 2015*

[7] *Reviewing the Real Costs of GMP Compliance; BioProcess International, Jun 2008*

[8] *Evaluating the Cost of Quality: It's Simple Math; Kari Miller, QMS , Global Tech Solutions, IQVIA Blog, Jun 02, 2020*

[9] *The blurred roles of our pharmaceutical regulators; K. Fierlbeck, Policy Options Politiques, July 13, 2016*

[10] *National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, A Proposed Rule by the Food and Drug Administration on 02/04/2022; Docket No. FDA-2020-N-1663*

[11] *Ensuring quality and integrity of vaccines throughout the cold chain: the role of temperature monitoring; Kartoglu & Ames, Expert Review of Vaccines, April 2022*

[12] *Guide to Good Distribution Practice of Medicinal Products for Human Use; HPRA 2021*

[13] *Getting More Value from Logistics Quality - optimising logistics quality management for efficient compliance, competitive advantage and customer value; Soulsby & Kennedy, International Pharmaceutical Industry, Spring 2022*

[14] *Delegate polls, MMCS GDP webinars in Luxembourg, UK, Korea, US, June 2021, July 2021, March 2022*

APPENDIX 2

GDP·UCI ADVISORY BOARD

- **Vincent Coolen** — ***Quality Assurance & Regulatory Affairs Director - UPS Healthcare***

  Vincent is a pragmatic, hands-on and solution focused QA Director who brings 35 years of industry experience to the Advisory Board, of which a big portion consists of international Quality Assurance & Regulatory Compliance expertise in Warehousing, Distribution & Supply Chain, in Europe, Asia, India and US.

- **Nigel Cryer** — ***Global Quality Audit Head - Sanofi Pasteur***

  Nigel currently leads all compliance and inspection readiness activities for Sanofi's combination products business, based in Normandy, France. Prior to Sanofi Nigel has a 30+ year body of experience in quality and compliance across the industry, including tenures at DHL Life Sciences (helping to set up the life sciences logistics unit), Roche, MSD, AstraZeneca and Norgine amongst others.

- **Sarah Graham** — ***QA Director, Supply Chain Systems & Programs - Abbvie***

  Working for one of the world's largest pharma companies and With a track record of more than than twenty years in global pharma supply chain quality management, Sarah brings extensive experience in GxP and quality assurance strategy.

- **Bob Hayes** — ***Vice Chair, Pharma Technical Activities Committee - IMechE***

  Bob has worked in the Pharmaceutical Industry for over thirty years. His experience includes Production and Engineering Management, New Product Development, Factory Design, Supply Chain Management, Validation and a variety of support functions. He has a special interest in the use of risk management and modern quality methodologies in the various aspects of regulatory compliance.

- **Alan Kennedy** — ***Director - Team Poseidon Ltd***

  Alan is a specialist in supply chain dynamics who, with his extensive cross-sector experience, is focused on bringing best-collaboration practice to pharma-logistics.

- **Andrew Lester** — ***Global Director, Healthcare - Expeditors***

  Responsible for healthcare business development at a global logistics company, Andrew comes with 3-decades of sharp-end experience in servicing the needs of demanding pharma clients.

- **Brett Marshall** — ***Corporate Head of Quality Assurance - Zuellig Pharma***

  Brett has spent the past 28 years working in Quality Management in Asia and leads a team of 300+ staff across 15 business units in 13 APAC countries. He is responsible for growing Zuellig Pharma's "Culture of Quality" in alignment with the company's strategic goal of making healthcare more accessible and ensuring product integrity & patient safety.

- **Roman Mijnhart** — ***Executive Director Quality - Ultragenyx Pharmaceuticals Inc.***

  Active in the biopharma industry since 1992 with different operational and Quality positions in the bio-manufacturing of vaccines and biologicals, Roman has a background in bioengineering, and has experience as a Qualified Person and GDP Responsible Person. He is open-0minded, pragmatic and in keeping a balance between regulatory compliance and product quality to secure product supply and patient safety.

- **Siegfried Schmitt** — ***Vice President Technical - Parexel***

  Siegfried has over 30 years of experience in the regulated healthcare industry. He provides consulting services to the healthcare industry on all aspects of regulatory compliance, particularly Quality Management Systems. Siegfried has a keen interest in the pharmaceutical supply chain and has written extensively on the subject..

- **Simon White** — ***Independent GDP consultant, Senior Advisor Medicines Quality, UN World Food Programme.***

  With more than 34 years broad experience in quality, safety and efficacy of biopharmaceuticals with one of the largest global pharmaceutical companies, Simon now helps supply chain organisations implement WHO GDP-compliant delivery processes for medicines and vaccines worldwide, with emphasis on underserved populations, challenging and high-risk environments. He is an elected Fellow of the Royal Society of Biology, FRSB (UK).

APPENDIX 3

FULL LIST OF CONSULTATION CLUSTER MEMBERS as at December 2022

Quality Specialist	CliniMed Ltd
Consultant Director	SeerPharma UK
Regional Manager Reefer Development – Asia Pacific	Kuehne + Nagel
Risk Control Manager	NMU
Responsible Person & Quality Assurance	Proctor & Gamble
Manager , Pharma & Special Cargo	Nigerian Aviation Handling Company Plc
CEO	TOWER Cold Chain Solutions
Executive VP, Pharma & Healthcare	JAS Worldwide
Standards Advisor	STANDARDS development
CEO	Hanse Service Internationale Fachspedition
Director Strategy & Business Development	CFL multimodal
AVP, Group Cargo Solutions	Port of Singapore Authority (PSA)
VP Pharma Healthcare	Leman A/S
QA&RA Director	UPS Healthcare
Responsible Person, GDP/Quality Manager Europe & UK	GEODIS
Director	One Wing Solutions
GxP Compliance Auditor	Reckitt
National Manager Healthcare Solutions	Aramex
Director, Consultant	GDP and Quality Matters Ltd
VP	Quality Academia
VP, LifeSciences & Healthcare	DHL
Quality Director	World Courier
Quality Assurance Senior Specialist	GDP and Quality Matters Ltd
Global Head, Quality (Healthcare)	Hellmann Worldwide Logistics
Global Head of Sales and Marketing	Tower Cold Chain Solutions
Senior Specialist QA	Amgen
Senior Associate Consultant	SeerPharma (UK)
Commercial Quality Lead	GSK
Vice President Risk Management	Marsh Ltd
Research and Development Scientist	DGP Intelsius
Responsible Person	Alcura UK Ltd
Senior Business Development Manager	CFL multimodal
Production Manager	BioGeneric Pharma SAE
Director External Affairs, JAPAC & LATAM	Amgen
CEO	Cold Chain Platform
Business Development Manager	DACHSER SE
Director	Klinge Corporation
National Pharma and Compliance Manager (RP)	Kuehne-Nagel Ltd
CEO	Web DeKo SARL
Senior Business Development Manager	CFL multimodal
Director Sourcing & Supply Chain	Calliditas Therapeutics AB
Marketing & Communications Manager	Emball'iso
Global Director, Healthcare	Expeditors
CEO & Founder	MCG Canada Inc. & MCG UK
Global Vice President, Healthcare Logistics	Hellmann Worldwide Logistics
Responsible Person	Smartway Pharmaceuticals Limited
VP Business Development	Orbcomm
Corporate Head of Quality	Zuellig Pharma Holdings Pte Ltd
Chief Commercial Officer & Supply Chain Project Director	COLCA Medical & Scientific
Ass. Director Distribution & Logistics Quality CoE	MSD
Global Director	Cold Chain Consultants Ltd
eHealth Expert	WHO
VP, Operations & Technical Services	Q Products & Services
Director and Consultant	GDP Pharma Consulting Ltd
Transport Qualification Manager	GSK
Regulatory Affairs Executive	Industry Body

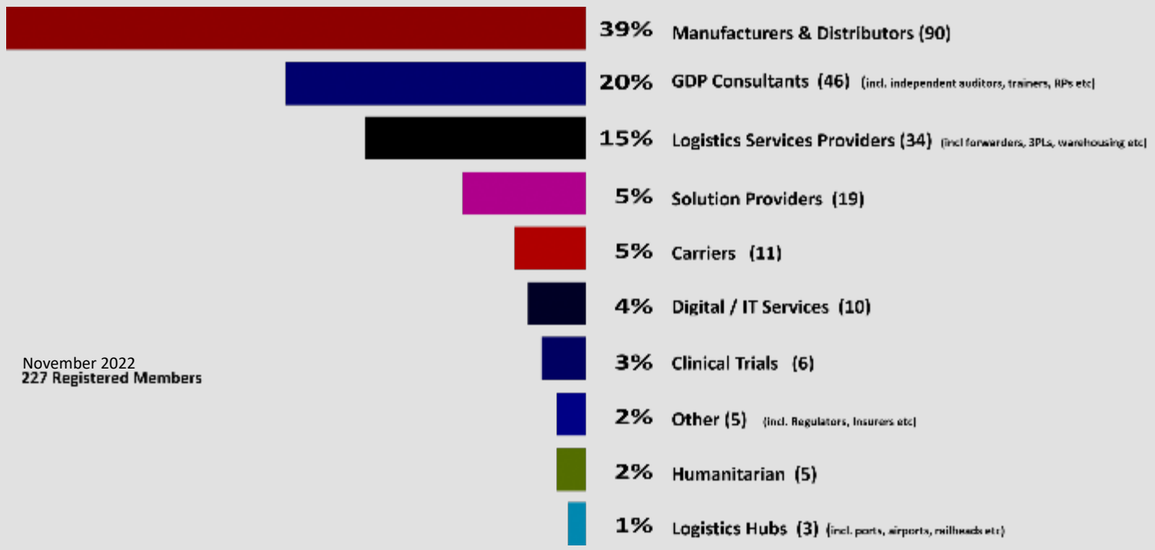
Quality & Compliance Manager,	GSK
Responsible Person	GSV Farmacêutica, Lda.
Director of Sales	Q Products and Services
Quality Assurance Manager	Novartis Pharma AG
Supply Chain Quality Assurance Manager	GSK
VP of Business Development	Controlant
European Healthcare Quality Manager	Yusen Logistics (Europe)
SVP, Global Quality Assurance and Operational Excellence	Marken
Chief Operating Officer	Mint Pharmaceuticals Inc
Director of Pharmacy Consulting Limited	GreenTech Investiment Holdings
International Logistics Director	Clover Biopharma
Head of Global Distribution Quality	Merck
Manager	ESPHARMAHUB
Director	Bisham Consulting
Quality and Regulatory Affairs Director	OCP Portugal
General Manager / Responsible Person	Nupharm Ltd / G-Pharma Ltd
Quality Manager	Transpharma International
Operations Manager	International Health Science
EHS lead	VESS Associates
Vice President Technical	Parexel
Head of Logistics	Merz Pharma GmbH & Co
RP	Callisto consulting
Director	GXPZONE Pharma Solutions Pvt Ltd
Quality Assurance Specialist	Medley Pharmaceuticals Ltd
CEO	Primaco
Independent Consultant	Independent consultant
Site Manager	VCK Logistics
Director, Global Reefer Competency Center	DHL
CEO	Tridentify
Director	Edatachase Ltd
QA Associate	Maersk Limited
Global Manufacturing Director	Cytiva
GLOBAL Group Manager - ArcticStore	TITAN Containers A/S
Associate Director, Global GDP Lead	Santen SA
Global Healthcare Quality Manager	Yusen Logistics
Head of Industry Vertical Healthcare Europe	Yusen Logistics
Technical Manager	TOWER Cold Chain Sulutions
General Manager -Cold Chain Operations	Reliance Retail (Pharma)
Responsible person and Warehouse manager	Abbvie
Quality Director	GSK
CEO	Mytigate GmbH
Account Manager	UPS
CEO	Aviapharm GmbH
Product owner	Validaide
Quality and Regulatory Manager	Kobayashi Healthcare Europe Limited
Director	High Fell Ltd
Responsible Person / GMDP Quality Consultant	Protogen Consulting Ltd
Director	Paul R Palmer Limited
Chief Pharmacist	Ashtons Hospital Pharmacy Services
Director Consultant GDP	Pharmasphere LTD
Head of Quality and Compliance/ Lead RP & WQP	Target Healthcare (Wholesale) Ltd
GDP Quality Consultant	GXPWAY
Managing Director	Global Pharma Solutions
Supply Chain Manager & Responsible Person	Kora Healthcare
Responsible Person	HH pharma & DE pharmaceuticals
Director	Hexagon Supply Chain
Technical Director	Healthcare Distribution Association
Deputy Responsible Person	Expeditors

President	Modality Solutions
Regional Auditing Mangager	Abbvie
GDP Quality Manager- The Americas	Expeditors
Responsible Person	Arian Medical Ltd
Associate Director, Global GDP Lead	Immunocore
Senior Quality Distribution Manager	Bristol-Myers Squibb
Pharmaceutical Consultant	Holotech (pending registration)
GDP responsible person	Lek Pharmaceuticals d.d.
CEO	Oosumi Logistics Co Ltd
Senior Health Compliance Manager	Crown Agents
Global Logistics Lead	Argenx
Responsible Person	Pharmafreight
Senior Warehouse and Distribution Expert	Zentiva
Strategic Development Director	Dawsongroup
Senior Consultant Pharma & MedTech	Log Konzept
Director	SeerPharma UK
Director & Senior Consultant	SeerPharma UK
Director	Q-support
Country Healthcare Quality & GDP Compliance Manager	Kuehne + Nagel Sdn Bhd
Head of Quality Management HCS	Grieshaber Logistics Group AG
Quality&Compliance Manager	Kintetsu World Express
Responsible Person and Quality Associate	Animalcare Ltd
Director Quality	Sanofi
Editor, Pharmaceutical Commerce	MJH Life Sciences
QA Director Supply Chain Systems & Programs	Abbvie
Chief Revenue Officer	TSS
EMEA Director Pharma and Healthcare	JAS Worldwide
Responsible Person	Remote Medical International
President	Crescentia and IM Cold Chain
Qualified Person	STM PHARMA PRO
President	Modality Solutions
Head of Department (Quality Management and Assurance)	Pharma Solutions Bangladesh Limited
QA Specialist Compliance	Amgen
Responsible Person/Quality Manager	Europort Pharmaceuticals B.V.
Senior QA Officer and RP	JensonR+
Project Manager	Dfe
Senior Manager Quality In-Market	GW Pharma (part of Jazz Pharmaceutical)
Head of Quality	JensonR+ Ltd
VP Engineering	AeroSafe Global
Associate Director, Global Freight & Logistics	AstraZeneca
Consultant	SRC2UK Ltd
Head of Logistics Quality	AstraZeneca
Head of Supply Chain Delivery	UK Department of Health and Social Care
Director of Product Development	LATAM Cargo
Responsible Person	Eisai
VP Quality & Compliance	QuickSTAT
Founder / CEO	Bonafi Ltd
Director of Compliance	Therismos
QA 7 Regulatory Conformance Manager	Parapharm Development Limited
Quality Specialist	HTF Associates
Responsible Person	HTF Associates Ltd
Senior Quality Manager	Bristol Myers Squibb
Senior Officer Quality Assurance	Oman Pharmaceutical Products Co LLC.
Global Logistics Lead	Teva
Logistics Services Manager	Almac Clinical Services
Deputy Director General	Industry Body
Quality and Compliance Manager	Ridgeway Biologicals

QAR	ACI Group Ltd
Principal Consultant	HumnoorBader Associates
Medicines Control Officer (GDP Inspector)	SAHPRA
Director	Van Stekelenburg Advisory Services
Business Manager Shippers & Forwarders	Port of Rotterdam
Senior Director Quality	ImmuCell Corporation
Secretary	Pharmaceutical Quality Group (PQG)
Senior Advisor Medicines Quality	United Nations
Vice President Global Sales	Berlinger & Co. AG
President and CEO	Extensio et Progressio SARL
Quality Assurance Lead	JSL SPC Katren
Principal Consultant	HumnoorBader Associates
Qualified Person	Chrinda BV
GDP Consultant and Responsible Person	Swift Ideas Ltd
Global Accounts Manager	Expeditors
Lead Auditor and Consultant	Audit Docs
Senior Quality Specialist	Controlant
Director	Coolchain Logistics
GDP QP	Adamed Czech Republic s.r.o.
Head Operations	Kaisha Life Sciences
RP	UK Ministry of Defence
Consultant	Freelance
GDP Manager	Reckitt Benckiser
QA Officer	Sigma Pharmaceuticals
QA & GDP Consultant	GXPWAY
Qualified Person	STM PHARMA PRO S.R.L.
Senior QA Auditor	ICON plc
Head Quality and GMP compliance	LM Manufacturing Limited
QMS consultant (GMP, GDP, medical devices)	Billev Pharma East
Consultant	Hanif Quality Consulting
Contract RP and Quality Consultant	Quality Consultancy
National Quality Healthcare and Compliance Manager	Kuehne + Nagel NV
Consultant	Milvus Consulting T/A Laing Pharma
Global Head Vaccine Corporate Quality	Sanofi Vaccines
Consultant	Trocchia SCM
Senior Technical Consultant	CCM28
Global Head of Operations	Tower Cold Chain Solutions
Innovation Director	CFL Multimodal
Quality Director	Lean Quality Consulting Ltd
Deputy Responsible Person - GDP pharmacist	Médecins Sans Frontières
Director	SeerPharma UK
Director	Medic pro limited
Co Founder and Active Chairman	CartaSense Ltd
Associated Director, Logistics	Charles River Laboratories
Head of Quality Assurance and Regulatory Affairs	DHL Supply Chain
Head of Corporate Infrastructure	PHOENIX Group
Director Technical Operations	Marken LLP
Head Quality / Responsible Person	Galexis AG
Quality Manager	McKesson Europe
Country Sales Director	JAS Forwarding
Head of Quality & RP	Spirit Medical
GDP Inspector Inspectorate Department	FSI, State Institute of Drugs & Good Practices
Founder & CEO	Consultancy
Head Special Cargo	IATA
Director and Senior GDP Consultant	Christa GDP Pharma Ltd
Chief Expert	Bulgarian Drug Agency / SW University, Sofia
Regulatory Conformance Manager	Parapharm Development Limited

APPENDIX 4

GDP·UCI CONSULTATION CLUSTER % BREAKDOWN BY CATEGORY



APPENDIX 5

Glossary of Terms, Acronyms and Definitions relating to the Manifesto content.

The following are adopted in this document:

CAPA: Corrective and preventive action (CAPA) consists of improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

Carrier: In the context of GDP-UCI, any company that physically transports pharmaceutical and related products from one place to another by any mode of transport. Airlines, shipping lines, rail operators, trucking companies and specialist couriers are all carriers. CCS: Compliance Certified Solution.

COQ: Cost of Quality. A measure of all the iosts relating to the quality of a product and its adherence to regulatory and in-house standards, guidelines and expectations.

DCSA: The U.S. Drug Supply Chain Security Act (2013).

Deviation: Any unwanted event that represents a departure from approved processes or procedures or instruction or specification or established standard or from what is required.

EMA: European Medicines Agency. An agency of the European Union (EU) in charge of the evaluation and supervision of pharmaceutical products

EUDRA GMDP: A database of the European Union Drug Regulatory Authority containing manufacturing, import and wholesale-distribution authorisations, and GMP and GDP licence certificates.

Excipient: A generally non-medicinal substance formulated alongside the active ingredient of a medication for a range of reasons including as a bulking agent or for hamdling purposes.

FDA: Food and Drug Administration. The federal agency responsible for protecting and promoting public health in the United States.

FMD: The Falsified Medicines Directive of the European Union.

Forwarder: A freight forwarder organizes shipments for a shipper. A forwarder does not move the goods but acts as an agent in the logistics network.

GAVI the Vaccine Alliance: A public–private global health partnership with the goal of increasing access to immunization in poor countries.

GDP: Good Distribution Practice and cGDP: A code of standards, in accordance with prevailing national and international legislations, ensuring that the quality of a medicine is maintained throughout the entire distribution process.. The prefix 'c' denotes 'current' emphasising the dynamic nature of these regulations.

GMP: Good Manufacturing Practice. The minimum standard that a medicines manufacturer must meet in their production processes.

GxP: A general abbreviation for "good 'x' practice". The 'x' denotes different quality guidelines/regulations e.g. GDP, GMP.

IATA CEIV: The Center of Excellence for Independent Validators in Pharmaceutical Logistics is a certification scheme for air transport pharma handling from the International Air Transport Association.

ICH: The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

KPI Key Performance Indicator: a measurable value that demonstrates how effectively a company is achieving key business objectives. Organizations use KPIs at multiple levels to evaluate their success at reaching targets.

LSP: Logistics Service Provider. A catch-all term describing any company that provides outsourced logistics services such as transport, warehousing, order fulfilment, customs clearance etc.

MAH: Marketing Authorisation Holder. The company or other legal entity that has the authorisation to market a medicine in a designated market or region.

MHRA: The Medicines and Healthcare products Regulatory Agency is the government agency regulating medicines and medical devices in the UK.NGO: Non-Governmental Organisation.

NCA: National Competent Authority: A government department or agency with vested, nominated or delegated responsibilities for certain legally-designated activities. In healthcare such matters might include the authorisation of medicines and the licensing of manufacturers and distributors. In Europe the NCAs work closely with the EMA as part of the European medicines regulatory network.

OOS: Out of Specification. A result that falls outside established and official acceptance criteria.

Operational Qualification (OQ): Documented verification that equipment or systems, as installed or modified, perform as intended throughout anticipated operating ranges.

PAHO: The Pan American Health Organization. The specialized international health agency for the Americas and serving as the regional representative of the WHO.

Performance Qualification (PQ): Documented verification that that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications.

PQS. Pharmaceutical Quality System. A rigorous system of quality management and risk control embracing, inter alia, GMP and GDP as exemplified by the international ICH Q10 model.

PWG: Primary Work Group. In the context of GDP-UCI ,this is a team of project participants tasked with undertaking a pre-defined core task, duty, or assignment relating to the program objectives

Qualification Protocol: A written and approved plan detailing how a qualification will be conducted including test parameters, product characteristics, equipment and acceptance criteria.

QRM: Quality Risk Management. A systematic, risk-based approach to quality management. The process is composed of the assessment, control, communication, and review of quality risks

QTA: Quality Technical Agreement: A contractual document that details the specific quality parameters for a project or service and explicitly stipulates the responsibilities of the parties concerned.

QUANGO: Quasi-Non-Governmental Organisation. An organization or agency that is financed by a government but that acts independently, or semi-independently of it.

PIC/S The Pharmaceutical Inspection Co-operation Scheme. An international instrument to improve co-operation and harmonisation in the field of GMP between regulatory authorities and the pharmaceutical industry.

SOP: Standard Operating Procedure: A set of instructions covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Collaboration Platform: The cloud-based communications and project management platform accessible to all registered GDP-UCI subscribers.

Qualification: The action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but individual qualification steps alone do not constitute process validation.

QBD: Quality by Design. A structured process for designing new products developed by the late quality guru Joseph Juran that focuses on the elimination of defects through advance planning and other pre-emptive measures.

QMS: Quality Management System. A formalized system that defines and documents processes, procedures, rules and responsibilities for achieving quality policies and objectives. ISO 9001 is an example of the criteria required for a formal QMS.

RCA: Root Cause Analysis. The process of systematically discovering the root cause of a problem in order to identify appropriate solutions.

Risk: The combination of the probability of occurrence of harm and the severity of that harm.

Risk Analysis: The estimation of the risk associated with identified hazards.

Risk Assessment: A systematic process of organising information to support a risk decision to be made within a risk management process.

Risk Management: The process of controlling risk through anticipating and controlling potential hazards by applying a through and ongoing process of risk awareness, identification, mitigation/removal and continuous review.

Shipper (Organisation): The business entity, normally a pharmaceutical manufacturer or distributor, that owns the products being shipped and pays for their transportation. The Shipper may transact with a forwarder or directly with carriers.

SIG: Special Interest Group: In the context of the GDP-UCI , the SIGs are mini-knowledge-hubs containing subject matter experts and other interested parties arranged as a support matrix. The SIGs act on an extempore basis providing ad-hoc assistance and advice to the PWGs as and when required.

Stability Data: The results of tests designed to determine the extent a drug product retains, within specified limits and throughout its period of storage and use, the same properties that it possessed at the time of manufacture. Such data are used in the evaluation of storage life and to assess the loss of potency and other detriments following undue temperature exposure and other events.

Storage Temperature: The temperature range listed on the pharmaceutical product label, and within the regulatory filings, for long-term storage.

Thermal Packaging: Types of protective packaging used to pack medicines and pharmaceutical products. Help prevent products from damage through temperature-induced potency loss or degradation.

Temperature Band: A predefined range of temperature used for monitoring pharmaceutical storage and transportation conditions to ensure that the product stay within known limits and their stability is assured. Common temperature bands are: +2°C to +8°C; +15°C to +25°C; There is currently no international harmonisation of temperature bands for pharma storage or transportation.

Temperature-Controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment, within precise pre-defined limits.

Temperature Excursion: An excursion event in which a pharmaceutical product is exposed to temperatures outside the temperature band or range prescribed for storage and/or transport.

US Centers for Disease Control and Prevention: The national public health agency of the United States. CDC is a federal agency and operates as part of the Department of Health and Human Services.

WDA: Wholesale Distribution Authorisation. This refers to the licence for approved drug wholesalers normally issued by NCAs and other regulatory authorities. The WDA permits a company to trade in medicines and, in Europe, the license holders can be inspected on the EUDRA GMDP database

WFP: World Food Program. An international organization within the United Nations that provides food assistance worldwide. It is the world's largest humanitarian organization.

WHO: The World Health Organization. A specialized agency of the United Nations responsible for international public health.

Temperature Profile: Anticipated ambient temperature variation and duration to which a pharmaceutical product may be exposed during transport.

Validation: A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting predetermined acceptance criteria.

Work Space: A space or 'room' on the web-based GDP-UCI Collaboration Platform dedicated to a particular PWG or SIG.

If you belong to and organisation that may be interested in participating in this important initiative please request registration details by e-mail from: **registration@gdp-uci.org**

GDP·UCI

Good Distribution Practice
Universal Compliance
Initiative

MANIFESTO