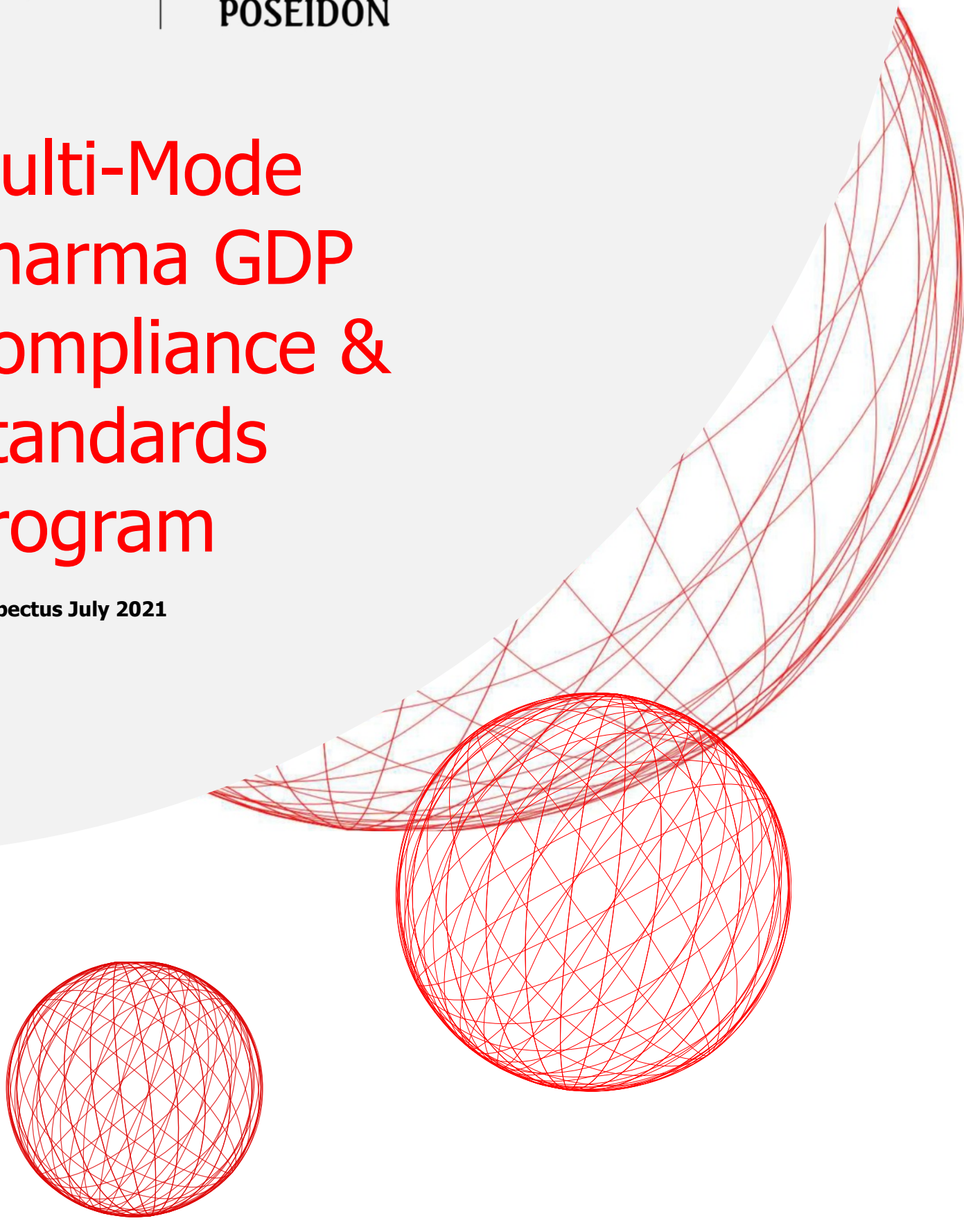
Multi-Mode Pharma GDP Compliance & Standards Program

Prospectus July 2021

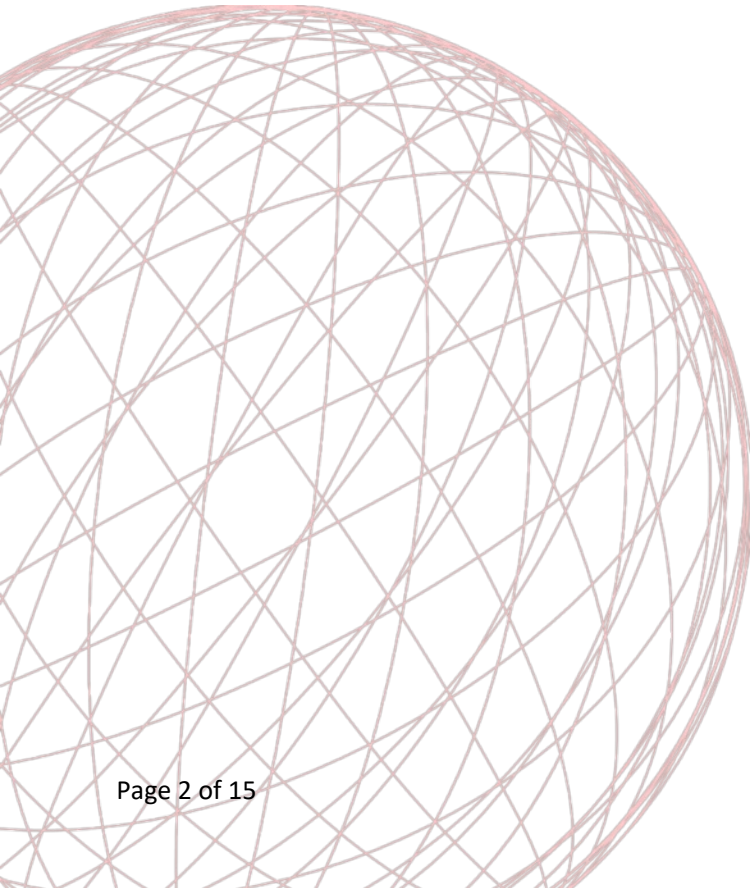


Inspiring trust for a more resilient world.

Why a BSI/Poseidon partnership?

The respective strengths of Poseidon and BSI will combine to produce a GDP capability that is unmatched in this sector of industry:

- Deep understanding of distribution routes and chain of custody in different transport modes
- Tested methodologies - supply chain risk management
- International standards and management systems frameworks to govern and manage distribution
- Compliance and certification - programme development experience
- Expert consultants in GDP, supply chain security, safety, and cyber security focused on pharmaceutical industry
- Global footprint to assess compliance of third-party distribution partners, manufacturers, and internal sites
- Technology to predict risk, manage KPIs / audits, and provide visibility of product from source to end-patient administration
- Market impartiality and competition safeguards stemming from the neutrality and independence of the two partners
- Experience of co-ordinating multi-party supply and logistics networks using efficient, cutting-edge collaboration tools and legally compliant supply-chain best-practice



Prospectus

Multi-Mode GDP Compliance & Standards Program – (MMCS)

Summary

This Prospectus describes a partnership between BSI (British Standards Institution) and Team Poseidon Ltd (Poseidon) with the goal of introducing an industry-wide GDP Multi-Mode Compliance & Standards program (hereinafter referred to as 'MMCS').

> *The need for rigorous compliance with regulations and strict adherence to best-practice surrounding the quality, safe, and efficient distribution of medicines and vaccines worldwide has never been greater. BSI, the National Standards Body, and Poseidon, the independent pharmaceutical logistics network, are bringing their joint resources and expertise together to develop and execute a Multi-Mode Compliance and Standards (MMCS) program to help promote, monitor and assess adherence to the GDP (Good Distribution Practice) regulations that underpin global pharmaceutical logistics.*

1 Business Case

What BSI Brings to Table:

- Recognition as a world-leader in the setting of technical standards
- Mature standards development, audit, certification and training capabilities
- Established expertise and track record in pharmaceutical supply chain
- The resource and infrastructure to execute on a global scale
- Expertise at setting up and running industry-wide best-practice, standards and compliance programmes

What Poseidon Brings to Table:

- Ready-built pharma logistics network as the foundation for the system.
- System structured around multi-party collaboration and best-practice - ideal environment for an integrated quality and compliance system.
- A legally compliant structure with respect to competition law and data protection (essential for audit share etc).
- An industry reform framework in which the BSI portfolio logically fits and where the whole is greater than the sum of its parts.

The MMCS Program is a holistic system coming from a partnership of the above two parties which will be endowed with a number of valuable USPs (see Page 9).

2 The Need

Manufactured medicines, or 'pharmaceuticals', are 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. These k'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.

The production of pharmaceuticals is often very large scale and tends to take place in a relatively small number of global production hubs. The output is frequently then distributed worldwide with the product quality and integrity being maintained through a system of enforced standards (Good Distribution Practice; generally referred to as 'GDP').

However, the logistics associated with the regulated distribution of these complex pharmaceuticals and their constituent ingredients is generally characterised by its byzantine nature, its structural fragmentation, and is high degree of regulatory oversight.

This all makes the management of quality and the adherence to regulations during distribution an absolutely critical part of the pharmaceutical supply process. However, as supply chains (especially as a result of pervasive outsourcing) get ever more convoluted and as drugs themselves become more complicated and labile, the overall control of quality throughout the process becomes increasingly difficult.

Some of the problems include:

- **Supply chain fragmentation** – logistics is one of the world's most fragmented industries rendering it notoriously difficult to control and change.
- **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, shifting demand patterns and capacity constraints 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 ingrained silo mentalities.
- **Security vulnerabilities** – these especially relate to counterfeit product, which is driving global track & trace legislation.
- **Poor consignment visibility** – this is another product of fragmentation which precludes dynamic product monitoring and timely interventions.
- **Lack of supply chain transparency** – the industry's congenital 'tunnel vision' and protectionism curtails co-operation and inhibits supply chain trust.
- **Training shortages** – Rising standards and regulatory demands have highlighted a dearth of adequate GDP training in many countries.
- **Sustainability issues** – the carbon footprint of sending medicines by air is of growing concern.
- **Technical standards** – the absence of universal technical standards is a growing impediment to the driving of sustained improvement across the sector.
- **Rising costs** – the explosion in freight rates, both air and sea, over recent times may, or may not, be a temporary aberration. But pharma companies are now being forced to look very closely at long-haul distribution costs.

"Simplicity is a prerequisite for reliability"*

Air freight is the default mode of transport for many pharmaceutical products mainly on account of its speed. However, this mode often attracts criticism for being over-complicated and this arguable over-complexity is the result of many interrelated factors. These include a hugely fragmented approach to Good Distribution Practice (GDP), the competitive instincts of suppliers that are compelled to offer differentiated products, the large number of hand-offs between independent supply-chain parties, the often dysfunctional relationships with, and between, third party operators, and the existence of an entire sub-industry of supply chain 'facilitators' with a vested interest in perpetuating the status quo.

It hardly makes sense for pharmaceutical companies to be:

- **each** finding, assessing and validating many different carriers and suppliers
- **each** developing and maintaining dozens of discrete OQ and PQ test protocols
- **each** designing a great number of in-house system assessments, product evaluations and qualification programs
- **each** conducting rigorous training programs for a multitude of ever-changing products and pack-out permutations
- **each** autonomously producing numerous individual lane validations
- **each** maintaining a library of disparate in-house SOPs and KPIs
- **each** using/developing proprietary digital booking and monitoring systems with often limited interoperability.

None of this makes sense because, although there will always be a need for highly specialist transport solutions for niche, very sensitive, and potentially dangerous pharmaceuticals, the vast majority of bulk prescription medicines and vaccines fit into one or two of just a small handful of recognised temperature bands and storage environments.

The fact is that, when it comes to the haulage of pharmaceuticals, most companies are essentially doing the same thing and they are all subject to the same (non-prescriptive) GDP regulations.

To use a motoring metaphor, the problem we have, is that all pharmaceutical companies and logistics providers, although using the same roadways and subject to the same Highway Code, currently have no option but to travel in custom-built vehicles that are hugely expensive and technically incompatible.

** Edsgar Dijkstra, 1930 - 2002*

3 Impact of COVID-19

The COVID-19 pandemic has served as a huge jolt to the pharma-logistics industry, revealing structural cracks and ingrained complacency in the legacy logistics model that have been long gestating. These deep-seated weaknesses have not just been exposed. they have been hugely exacerbated by the COVID-19 pandemic, with the implications promising to be very far-reaching for the logistics industry.

4 The Opportunity

Nonetheless, if there is one thing this pandemic has taught us, it is the value and benefit that can be gained by harnessing the collective, skills, knowledge and resources of multiple stakeholders in the face of a problem which is beyond the might of any individual organisation.

The window is open for a sea-change in the way pharmaceuticals are distributed. However, such a reformed supply chain model needs to be underpinned by a support programme that drives improvements in quality, productivity and performance measurement.

The MMCS program represents a radical system that will fill the void in the market for a more universal, harmonised and standards-driven approach to quality, qualification and training in the distribution of vaccines and other medicines.

The MMCS model will:

- Greatly simplify the quality compliance processes, especially from a shipper's perspective.
- Remove a huge amount of duplicated effort, overlap and repetition amongst pharma companies.
- Proactively attenuate some of the risk inherent in the pharma logistics process.
- Introduce standardisation of player, process, product and system.
- Serve to bring the pharmaceutical companies together to minimise process divergence, aggregate volumes, share resources and collectively innovate.
- Reduce the high number of quality and regulatory non-conformances.
- Provide shippers and LSPs with a common reference point for continuous improvement in quality and compliance.
- Integrate seamlessly into both the legacy and Poseidon logistics systems.
- Reduce costs as a result of standardisation and economies of scale.

5 Description of the MMCS Model

The MMCS program is a universal GDP quality compliance scheme predicated on:

- Standardisation – process (incl. SOPs), product, system
- Universal technical standards for key supply chain elements
- Continuous improvement
- Universal supply chain audits
- Enhanced physical security
- Robust digital security
- Comprehensive training support
- Integrated last mile distribution
- Sustainability compliant

Target Audiences

The approval and endorsement of industry regulators, trade bodies, shippers and others involved in defining requirements will encourage the stipulation of MMCS standards and guidelines in quality specifications and terms of conformance.

Normally, the responsibility for the quality of a drug and ensuring that its related value chains are in compliance with the appropriate regulations is the legal responsibility of the 'Marketing Authorisation Holder' (MAH) in conjunction with its licenced wholesale distributors (WDA) in a particular country. (Note: the MAH is often the drug manufacturer although in the case of sub-contracted production the MAH may be the commissioning principal.)

GDP puts the responsibility on the MAH 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".**

Therefore, it is essential that MAHs and WDAs (and the regulating authorities) are aware of the new program and subscribe to its universal approach.

Such acknowledgement and adoption will encourage the rest of the supply chain to engage with the programme for reasons including:

- as an element of a Quality Agreement
- as an independent seal of approval to increase the appeal of suppliers and carriers to prospective clients
- because it will reduce the exposure of shippers, carriers, forwarders and suppliers to superfluous quality inspections
- because it is required as a vendor pre-qualification

The Program is consequently of direct relevance to the entire global pharmaceutical industry.

**Guide to Good Distribution Practice of Medicinal Products for Human Use HPRA IA-G0046-210, March 2021*

Objectives & Goals

Overall Program Objectives:

- **International Industry-Wide Recognition**
  To be recognised industry-wide and internationally for the highest standards of compliance with GDP regulations and guidelines.

  To become a de-facto global standard for GDP quality management support in the pharmaceutical supply chain space.

- **GDP Simplification**
  To be a universal, one-stop-shop, system for managing the quality and regulatory-compliance aspects of distributing medicines globally that is comprehensive and joined-up, yet straightforward to use.

- **Certainty, Uniformity and Universality**
  To provide a greater degree of GDP certainty, consistency and peace of mind throughout the pharma logistics chain. The current disjointed and fragmentary nature of pharma-logistics can only be solved through greater standardisation, unification and collaboration.

- **Accessibility**
  To be designed and structured to be accessible, using the latest technologies and local partners in all regions in the world.

Simplifying 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.

- **Affordability**
  To reduce the costs of compliance right along the value-chain ensuring broad program take-up and uniformly elevated standards.

- **Adaptability**
  To have the flexibility to cope with changing market conditions, align with national GDP variants, react to technical and market disruptions, and be relevant to different corporate structures and priorities.

- **Scale and Scalability**
  To be global in scope and designed for rapid scalability to meet demand.

Program USPs

The MMCS program will differ from other system compliance-support systems that are in place or have been mooted for the following reasons:

- **Neutrality and Independence**
  The impartiality of the MMCS program will proffer a huge commercial advantage by making it attractive to both shippers and regulators.

- **Universal in scope (multi-modal)**
  An integrated program that is multi-modal in scope is a very attractive proposition, especial for shippers, since it facilitates the optimum choice of transportation and facilitates good quality management.

Why Certification is not enough

Although certification schemes have an important role to play in raising standards, many of these schemes are far from perfect and are delivering questionable results. In fact, industry is littered with failed or poor certification schemes.

Such schemes may inculcate a false sense of security, they can encourage 'workarounds' and 'window dressing', they are associated with high compliance costs and they are often ridden with conflicts of interest.

- **More than certification**
  Executed correctly, certification can be a useful tool in the GDP compliance armoury. However, many certification schemes fall short on their primary purpose (see Box above).

  The MMCS Program will be a single port-of-call for all the main elements of compliance – technical standards, certification, validations, qualifications, training, audits etc. And, with its links to the Poseidon initiative, MMCS will be an integral part of a broader movement for reform which will broaden its appeal.

All of these MMCS USP's come together to create an unassailable business case from the user perspective.

6 Program Structure and Project Elements

Standards / Guidelines

Standards are independent documents created to provide guidance or outline requirements / specifications. The existing Poseidon technical process and risk documentation, together with input from the MMCS consultation and other sources, will help shape and inform the development of overarching industry standard(s).

GDP Compliancy

The requirement for pharma to comply with GDP creates a regulatory-driven need for pharmacos to verify their supply chain competence. Therefore, the shipper is usually the audit instigator. However, shippers themselves are an integral part of any compliance system and must periodically undergo assessment themselves.

For these purposes the idea of a standard 'MMCS Compliancy Score' appears to have merit since MMCS is more about continuous improvement than certification as an end to itself.

Such a universal compliance scheme will be modular in design and embrace:

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

With modules specific to:

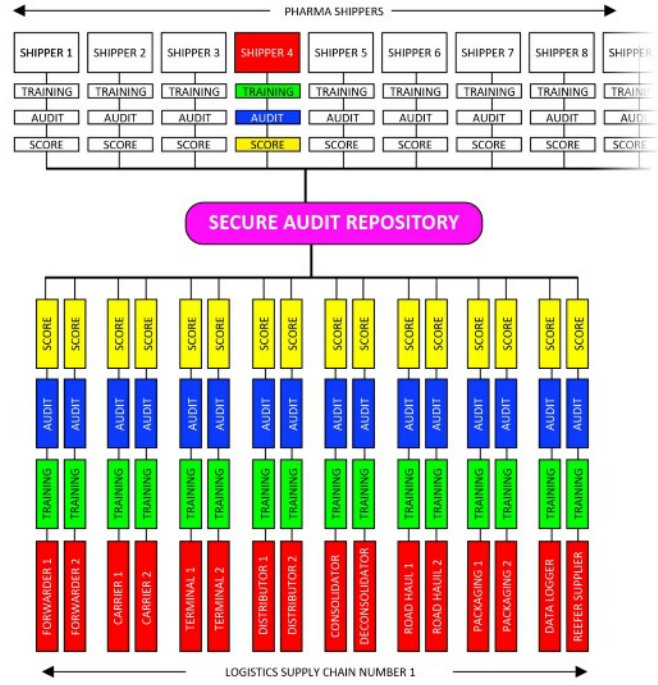
- Shippers/consignees
- Carriers – lines, overland
- Storage/handling
- LSPs – forwarders, distributors etc.
- Suppliers

Audit Scheme

An audit scheme is an important element of the MMCS program as part of a consistent universal industry standard for GDP-compliancy.

For example, this will mean that a single supplier audit will convey an industry-recognised compliancy status that will be universally valid amongst multiple shippers. (Fig 1.)

Fig 1.



In other words, the industry will mutually accept the results and the supplier will not be subject to multiple audits from different principals. Re-audits will be undertaken at set intervals e.g. every three years.

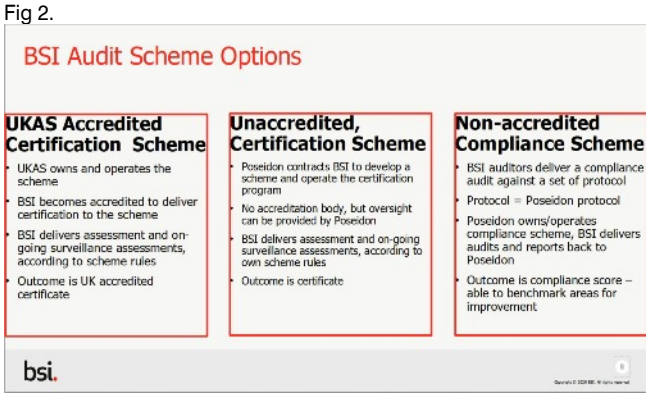
Choice of Audit Scheme

A number of audit options are available and the the assessment scheme can have various outputs (Fig 2.):

- Facility Compliance score, with NCs raised
- Distribution lane compliance and risk score, with NCs raised

- Granting of a Certificate for sites and their scope of certification, backed by accreditation body
- Granting of a Certificate for sites and their scope of certification, not backed by accreditation body
- Possibility for additional options.

Fig 2.

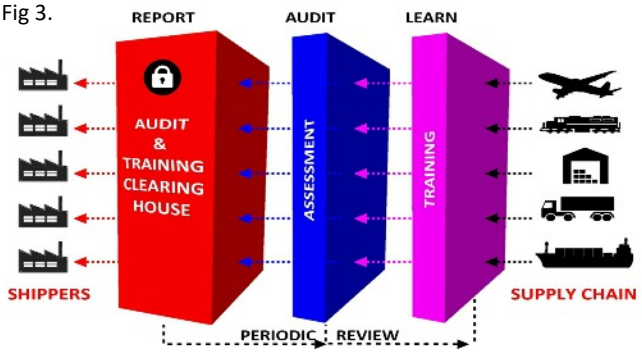


Shared Audit Platform

The system for sharing audit results needs careful consideration re data management and security. See Fig 3. The independent status of BSI and Poseidon will be critical in this respect.

Training

Fig 3.



The MMCS training dimension will be conducted as a category within the established BSI training school. See Fig 4.

Training program characteristics:

- A modular training programme covering the end-to-end freight process
- Geographical coverage: global
- Aimed at all actors in the pharma logistics supply chain with initial focus on pharma shippers
- Multi-modal in scope: incl. the training needs for co-loading, cross-docking, and combined transport shipping

Fig 4.

Training Content

In addition to supply chain management education, the industry needs operational guidance including:

- GDP - regulatory compliance
- SOP - specific training
- Quality and Risk Management – QMS, mitigation, qualification/validation etc.
- International standards and best practice
- Personnel – RPs, roles / responsibilities
- Premises – environment /temperature control, dock handling, consignment preparation, conditioning, stuffing, loading etc
- Co-loading – consolidation / deconsolidation best practice
- Documentation & change control
- Operations – storage
- Internal Audits
- Equipment and systems – containers, labelling, protection, packaging, conditioning, monitoring, tracking – etc.

7 Roadmap and Timescales

A draft Year 1 roadmap and timeline can be found in the Appendix.

8 Marketing

BSI's marketing team will drive the development and creation of MMCS marketing documentation and value proposition materials, to support external engagement. The BSI sector team will work closely with Poseidon to engage industry stakeholders to raise awareness of the MMCS compliance scheme with regulatory and advisory bodies such as USP, PDA, ICH, WHO, EMA etc.

11 Industry Consultation

Having been conceived as a global, industry-wide initiative it is important that BSI and Poseidon solicit as much intelligence as they can from the field to ensure that the program accurately reflects the quality, compliance and GDP needs and priorities of this rapidly changing market place.

Market engagement is being commenced through the establishment of a 'MMCS 'Consultation Cluster' where interested parties will be kept up-to-date and given the opportunity to be involved in the program. This will entail activities such as discussion groups, workshops, surveys and pilot exercises.

In addition, it is intended to establish a MMCS Market Liaison Committee (MLC). The role of the MLC will be to represent and communicate / collaborate with the various target industry sectors and markets and it will have a responsibility for establishing Stakeholder Focus Groups (SFCs):

- Mode/Carrier Representatives:
- Air, Ocean, Rail, Road,
- Airports, Ports, Terminal Ops, Ground Handlers etc
- Pharma Shippers/consignees:
- Vaccines, Biologics, Small Mol, Generics, Distributors
- Regional Representatives:
- Europe, North America, Latin America, Africa, Middle East, India, East Asia, South East Asia/Oceania
- Regulators
- LSPs – forwarders, Distributors etc.
- Suppliers – Products/Systems/IT

About BSI

For over a century BSI has driven best practice in organizations around the world.

Working with over 77,500 clients across 195 countries, it is a truly global business with skills and experience across all sectors including pharmaceutical sector. Incorporated by Royal Charter, BSI is the UK's national standards body and leader in its expertise in Standards and Knowledge, Assurance Services, Regulatory Services and Consulting Services.

With headquarters in London, BSI has authored many of the world's most widely adopted technical and management standards, such as ISO 9001, and ISO 14001.

BSI not only drives standards and risk management solutions but is also the lead partner in several industry-wide compliance networks/ collaboration programs such as the Supplier Compliance Audit Network (SCAN) and the RX360 Life Sciences Consortium.

About Poseidon

Established in 2017, the Poseidon program is an industry reform initiative conceived to develop and improve the safe, efficient and compliant long-haul transportation of pharmaceutical products.

This is being achieved through the application of contemporary supply chain best-practice and structured, multi-party strategic collaboration.

The unique Poseidon model is built around managed strategic partnerships directly driven by the safety, quality, performance and other needs of the pharma-manufacturer. Its strength rests in the collective energy and resource of its end-to-end engagement, its intimate commercial alignment and its 'one-team' culture. All based around the principles of win-win relationships, supply-chain discipline, shared risk, mutual strategic targets, focused effort, end-to-end transparency and continuous improvement.

Poseidon is open to all shippers of pharmaceutical finished products and ingredients.

Multi-modal GDP Compliance Program

OUTLINE
YEAR-ONE ROADMAP

① **CONFIRM PROJECT DEFINITION, SCOPE, TIMELINE**
Statement of scope / purpose for internal and marketing purposes
PRIORITY: Create & Agree Roll-out Schedule

② **DEVELOP & AGREE BSI/POSEIDON RELATIONSHIP**
PRIORITY: Agree Roles & Responsibilities
IP Ownership & Protection
Commercial Model BSI/Poseidon

③ **CONFIGURE ORGANISATIONAL STRUCTURE**
PRIORITY: Establish Governing Body - BSI/Poseidon
Establish Technical Committee(s)
Create Advisory Board/Liaison Committee
- Invite Pharma Companies & Other Stakeholders

④ **CREATE PROGRAM AWARENESS**
PRIORITY: Marketing Campaign:
- Branding
  - Program Name, Logo
- Announcements
  - Internal, Press
- Launch events
  - C4L Conference, Others
- Materials
  - Program Process Map / Infographic
  - Program / Concept Brochure
  - Program Presentation(s)

Promotion
- Press & Social Media
- Conferences & Events

⑤ **COURT INDUSTRY ENGAGEMENT**
Marketing Program:
- Establish Stakeholder Focus Groups
- Workshop Program for Select Target Audiences:
  - Shippers/Consignees
  - Regulators
  - Carriers - shipping lines, overland
  - Terminal Operators
  - LSPs - forwarders, distributors etc.
  - Suppliers

⑥ **DEVELOP PROGRAM ELEMENTS**

⑦ **TRAINING**
PRIORITY: Positioning in BSI Training School
- Map program requirements to existing BSI course portfolio

New Course Identification & Development:
- GDP Risk & Quality Management
- Operational
- Auditing
- Mode-Specific Training Requirements

Training Platform/Regional Hubs
Design and Implement Pilot Training Course
Identify Pilot Participants

⑧ **INDUSTRY STANDARDS & STANDARDISATION**
PRIORITY: Determine Standards Strategy
- Topics & Types

Establish Standards Committee(s)
Develop:
- Technical Standards & Guidelines
- Solution Specifications
- Process Guidelines
- SOPs

⑨ **ASSESSMENT**
Devise Audit & Certification Scheme:
- Compliancy Scoring System
- Audits - universal
- Choice of audit scheme
- Audit platform & Scheduling
- Supplier/Carrier Certification
- Products/Systems Qualification
- Lane Validation
- Supply Chain Compliance

PRIORITY: Design Draft Audit Scheme and Pilot

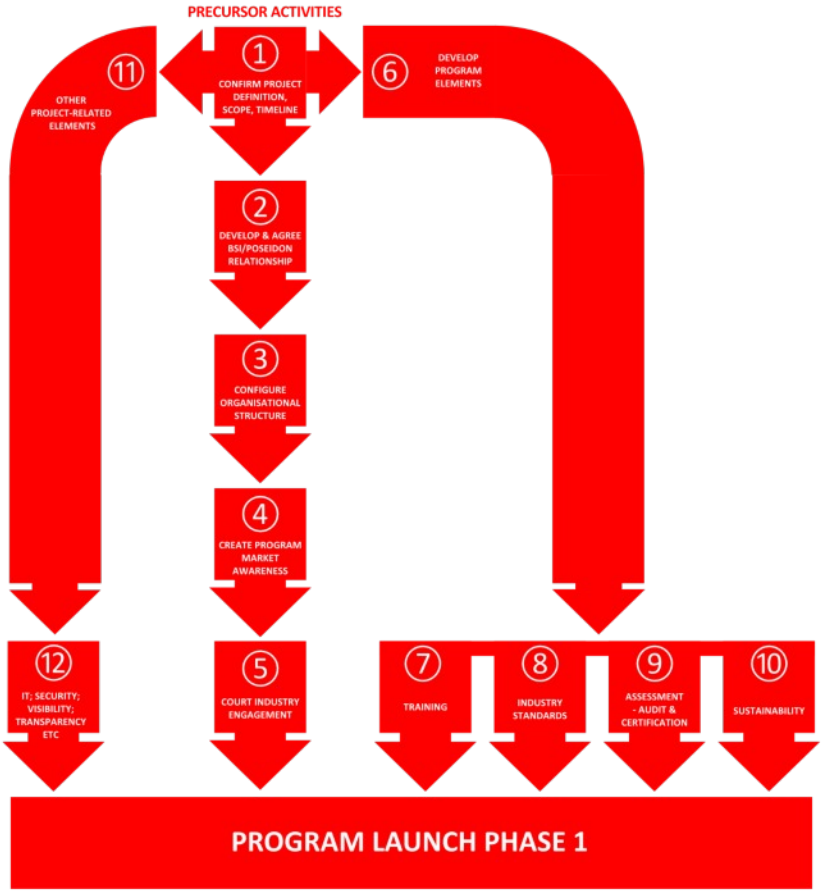
⑩ **ENVIRONMENTAL**
TBA

⑪ **OTHER PROJECT - RELATED ELEMENTS**

⑫ Program IT
- Digital Platforms

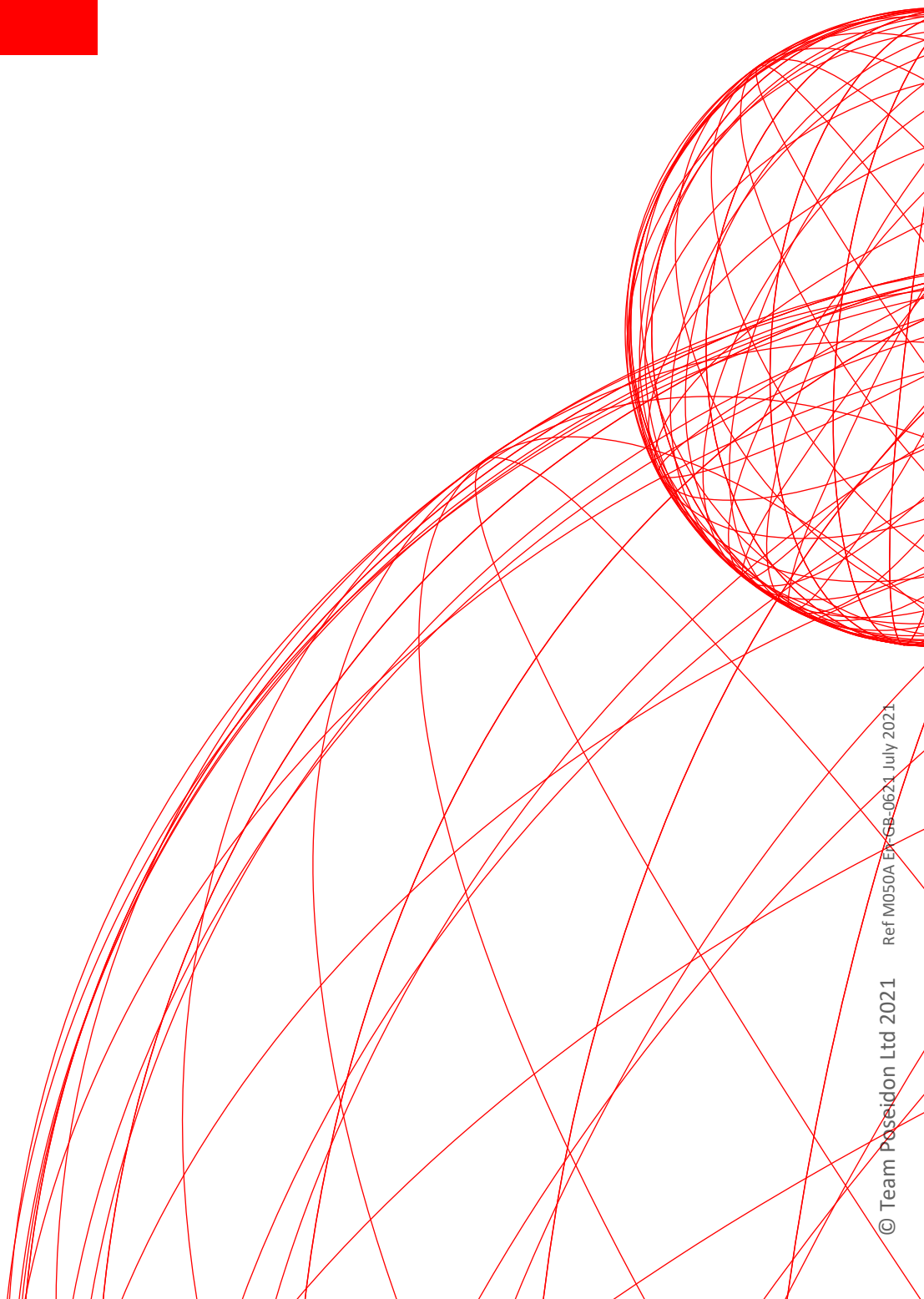
Shipment Security
- Audit results

Shipment Visibility
- Program Integration



GDP Multi-Mode Compliance & Standards

Aimed at pharmaceutical shippers and the entire distribution chain, the GDP Multi-Mode Compliance & Standards program is designed to bring consistency, certainty, and continuous improvement to the process of meeting international quality and regulatory standards for the safe, efficient and sustainable distribution of medicines and vaccines.



Disclaimer

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