Building Global QA System and Compliance – Advantage for the Customer

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The PolyPeptide Group (PPL) is an international manufacturer of peptide-based active pharmaceutical ingredients with six facilities worldwide (Denmark – France – India – Sweden - USA). Being a global group is a challenge in many aspects and thus a number of improvements within the organisation need to be addressed. These include a change in thinking, from many locally oriented businesses transformed into one huge global player in a highly competitive market in order to best serve the customer. From a QA perspective this means that many local systems need to harmonized into one global system. This article briefly outlines the PPL approach in this endeavour.

Background

The PolyPeptide (PPL) Group, is a Contract Manufacturing Organisation, consisting of six (6) individual sites, each of which specializes in peptide manufacturing and development. PPL supports many peptide projects from small-scale, non-GMP manufacturing, through development, to large-scale, commercial manufacturing carried out in fully GMP compliant facilities.

Historically the sites have matured more or less independently from each other. This also means that individual quality systems have been developed and maintained locally over the years.

PPL is now taking the steps to implement harmonized systems across the group in order to generate operational consistency and regulatory compliance for the satisfaction of our customers and as a step forward into being a truly united organization. The goal is to 'transform' PPL into a more unified entity based on the business segments each unit represents. We have identified many opportunities for synergies and believe that these changes will strengthen the company internally and externally in the long term and thus leading to huge benefits for our customers.

Why have shared systems – Advantages

As a leading contract manufacturer of peptides, the PPL Group is always looking for improvements in order to stay ahead of its competition within its business segments. For this reason we want to position ourselves based on the technical and regulatory experience accumulated over the past many years. Our primary objective is to support its customer requirements and expectations even better, and work in a more integrated manner with each of our multiple customers. The importance of short lead-times, strong know-how, flexible and consistent QA/RA systems in symbiosis with strong customer appeal are just a few aspects in this matter.

Designing and deploying harmonised quality systems definitely is one of the key ingredients in this approach. PPL wants to be able to offer all our customers the same high level of quality & service whilst meeting and exceeding the standard regulatory requirement levels of quality irrespective of site location. In effect, this practical approach allows all of our customers to clearly see the benefits of the alignment in the shared systems, especially where projects may be manufactured at multiple sites across the organisation in exactly the same superior manner. Subsequently, from a customer audit perspective the auditors will be familiar with the quality systems regardless of the location of the manufacturing site. This alone is a tremendous advantage for the customer and the organisation.

Additional Advantages:

- Create synergies, transparency, independency and common understanding across the organisation
- Standardize Quality practices to support business processes globally where applicable – smooth product and method transfers, consistent approach etc.
- Facilitate communication between groups globally.
- Ensure awareness of current regulations globally and proactively implement appropriate systems to ensure compliance.
- Improve PPL documentation – focus on need-to-have from a process perspective.
- Improve business awareness.
- Form a foundation and discipline for global improvement activities.
- Employ a Quality System which is owned by the PPL Group rather than individual sites or a functional area.

Having all these elements maintained and challenged consistently are a key factor in allowing PPL to become an even more attractive, reliable and preferred business partner in the peptide business.

Strategy

The first priority for Global QA was to identify and establish the QA Strategy. Once the Strategy was defined each site knew exactly what to expect and how the global QA system would be deployed. The philosophy behind the strategy was not to start all over from scratch, but instead to leverage best practices and reshape the system where feasible and suitable for the business. Though flexibility and pragmatism should be ensured throughout the life cycle stages, changes must be consistent with current regulatory requirements.

However, structure, commitment and discipline are essential ground rules in this process and must be fully adhered to in order to maintain momentum and focus. For this reason thorough planning was essential for implementation.

The PPL QA strategy consists of the following elements:

- Define and establish an overall PPL Global Quality Policy
- Develop and implement a Global Quality Manual
- Define elements and structures of the Quality Management System (QMS)
- Assign system owners and resources
- Map out current processes across the organisation and identify potential gaps
- Organise and prioritise the work
- Select a system, review current practices, define future practices and implement them
- Create global templates and forms
- Monitor and report progress on a regular basis in management meetings
- Evaluation of implementation through the PPL self inspection program

The implementation of a Global QMS is a stepwise and often a time consuming process, as resources are limited. Thus, in order to ensure momentum and focus a limited number of QS activities can only be addressed at any one time. Short deadlines and dedicated effort are key to this approach.

The prioritisation of the work is based on what is identified as the most pressing needs either deriving from customer input, regulatory commitments or projects across sites that have a clear advantage for the Group and our customers.

The global quality system within PPL is based on the obligation of clinical trial sponsors and of drug product manufacturing authorisation holders to use only drug substances that have been manufactured in compliance with GMP. The principles of GMP for drug substances are taken from ICH Q7, Good Manufacturing Practice for Active Pharmaceutical Ingredients, and are adapted to meet the expectations of ICH Q8, Q9, and Q10 which are relevant to drug substance manufacturing.

Development of the QS must be a joint effort across the organisation and requires commitment responsibility and resources. The overall process is facilitated and coordinated mainly by the Global QA team but also with strong involvement by other organisation units. As a result, system owners are appointed to the individual systems. The system owners, and thus the responsibility for the system, are spread across the organisation.

How it is done

Moving from a local to a global approach is something that requires a number of considerations in order to gradually change the way of working. The "old way" of doing things may not be the same tomorrow. Henceforth the challenge within the organisation is to inspire and change the mindset to think in a global and far-reaching manner, rather than local. It is a process that takes time given the diverse history of the company.

Internal communication
An essential element is to communicate the changes that are needed, as well as their impact and consequences for the company and the individual employees. Changes should be seen and considered a natural part of the organisation's work habits and driver for success in order to facilitate and promote continual improvements.

Involvement of all personnel
These global changes should not be "wrapped in mystery" but regarded as everybody's responsibility within the organisation where people find motivation and inspiration, and recognise the importance of the work ahead.

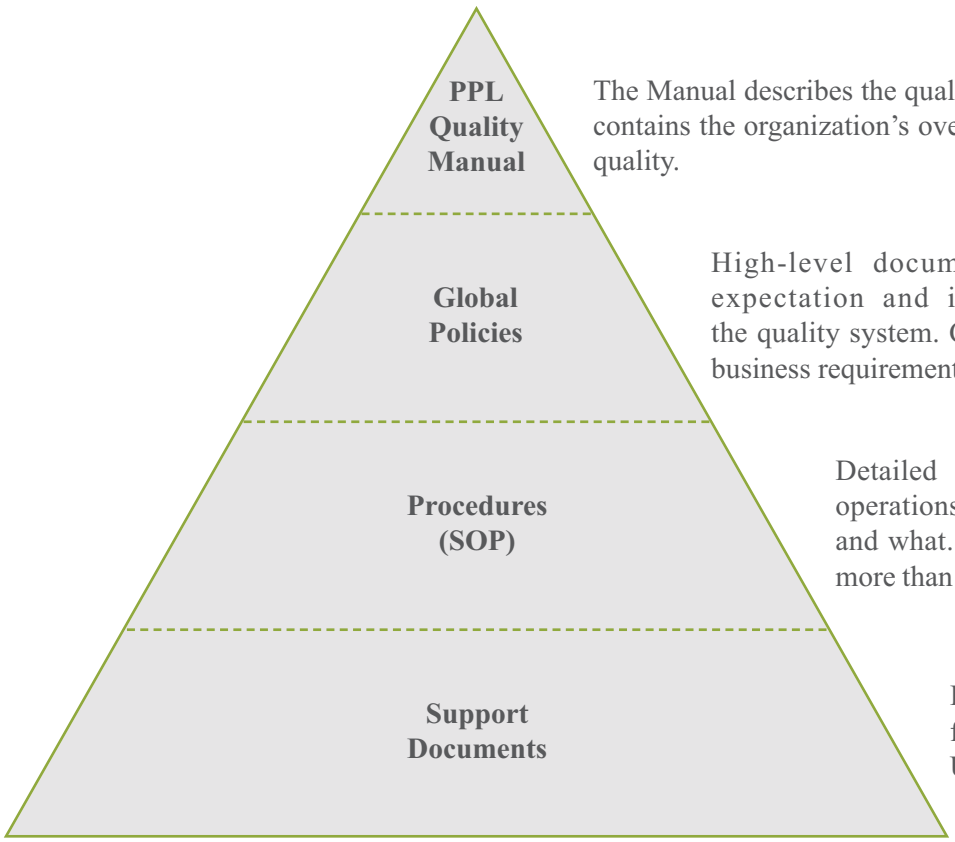
Strong Management
This calls for a strong management team that promotes supports and shows the path forward in this approach.
Fundamentally we embrace the importance of teamwork and encourages cooperation, collaboration and communication at all levels and across all functions as the basic drivers. In effect, this is literally reshaping the culture within the company by adding the global layer. In essence the mission is to foster a culture of collaboration and improvement throughout the organisation in order to achieve the objectives.

Initially the first step was to introduce a global organisation within the disciplines of Sourcing, Sales & Marketing, IT, Project Engineering, Regulatory Affairs, Technical Operations and QA. In other words - the global backbone of the Organisation has been determined.

On a regular basis management meetings are scheduled in order to discuss projects, set directions and evaluate general progress. This is performed to ensure that the program does not get sidetracked or lose focus during the process.

Importance of the documentation management; it must be simple, well structured and constitutes the framework of the whole system.

The PPL System hierarchy now looks as follows:



The Manual describes the quality system of the organization and also contains the organization's overall commitment and policy regarding quality.

High-level document outlining the organization's expectation and interpretation of a given element in the quality system. Contains the minimum regulatory and business requirements.

Detailed documents that describe "How" operations are performed by whom, when and what. These documents can either apply to more than one site or remain as a local document.

Included are documents such as forms, templates, specifications, User manuals etc.

Since the harmonisation and globalisation process was initiated in 2010 the following activities have been accomplished:

- Mapped out current processes across the organisation and identified potential gaps.
- Identified and prioritised the system elements to be harmonised, i.e. developed shared best practices across the group
- Issued a Global Quality Manual,
- Created global templates and practices (For Global Policy, Global SOPs and Quality Agreements)

Specific system elements that have been completed pertain to global supplier audits and qualification. Global policies have been generated and issued for Process Validation, Stability programmes and Product Quality Review (PQR,) and we are now in the final step of introducing Global SOPs relating to risk assessment in Development.

In conjunction with Global sourcing we are now in the phase of implementing global specifications, which not only will harmonize the quality of the starting materials and of the finished products over the sites, but will also ease the regulatory work and the transfer of projects. Additionally, from a cost and purchase perspective we anticipate savings in the years to come as well as cost efficient QC analysis due to centralized work processes.

Customer feedback

This new journey has just begun and there is still a long way to go. Nevertheless, based on the current accomplishments due to these changes we have received only positive feedback from our customers. When a project involves more than one site, customers will start to observe certain commonalities and alignments within our quality systems despite the location. From a customer audit and business perspective this is clearly seen as a huge advantage to the customer.

Next step forward

Continuous improvement encompasses both incremental improvements within the existing processes and may result in significant changes to process design.

Introduction and definition of overall Global QA Key Performance Indicators (KPI's) are in the early phase of establishment with the purpose of measuring performance metrics across the group and these will continue to be analysed and further developed in the future. However, more site specific KPI's and metrics will also be handled locally.

An important aspect in the development of the system is how we link things together. Currently, PPL basically operates with a paper-based system; however, decisions have been taken to introduce and implement an Electronic Document Management System which will be a platform where all documents are created, maintained, retired, and used as a mechanism to promote the global communication and globalisation process in general.

Conclusion

Implementation of the global quality system will ensure PPL's ability to consistently provide products that meet customer needs and applicable regulatory requirements. The global system includes processes for continuous improvement of the organization, its products, services and the quality system. The management system will control and be accountable for the efficient organization of the processes that create the products or services and ensure that proper planning, monitoring and improvement take place. Company results and customer feedback are already proving that this is creating a strong win-win strategy between PPL and our customers.

Author Profile

Henrik Schou Sørensen is the Global QA Director at PolyPeptide. He joined the Group in 2009, bringing with him a broad background in quality systems. Today, he is working to develop a uniform global quality platform accross the PolyPeptide Group.