IT'S ALL IN THE PACKAGING

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Present the new standard for pharmaceutical packaging materials, PS 9000:2011

Patients using medicinal products have little chance of detecting if they are faulty or not. People who take a medicine rely on the doctor who wrote the prescription and the distributor who dispenses it to ensure it is of appropriate quality. The same principle also applies to medicines purchased over the counter. The doctor, pharmacist and also the consumer put their trust in the manufacturer and the supply chain, who have fundamental roles in ensuring that the medicinal product is fit for its purpose and is safe to use.

Traditionally Good Manufacturing Practice (GMP) was only applicable to the manufacturers of medicinal products, but the quality of the products can only be assured if controls are also applied to the constituent components.

The new PS 9000:2011 standard will strengthen control and reduce risk within the pharmaceutical supply chain"

The Pharmaceutical Quality Group (PQG), the longest established special interest group of the Chartered Quality Institute, has focused on meeting the needs of the industry and quality professionals alike and has been instrumental in the development of monographs and standards for both the pharmaceutical industry and its supply chain. With the ever-changing expectations of the regulating bodies for medicinal product manufacturers, the publication of ISO 15378 "Primary packaging materials for medicinal products", and technological advancements, in 2008 the PQC initiated a two-year consultation process for the development of a new GMP standard. The team, tasked with evolving the standard, was formed from a diverse range of interested stakeholder companies, which included representatives from pharmaceutical manufacturers, contract packing organizations, primary and secondary packaging suppliers, consultants and origination or artwork studios. The diversity of the established team ensured a balanced representation of the industry, bringing together expert knowledge, skills and experience. The result of this can be seen by users as they navigate through the new PS 9000:2011 standard, which both the PQG and industry regulators believe will only strengthen control and reduce risk within the supply chain, including the risk of counterfeit drug products.

Origins

In 1990, following collaboration with both manufacturers and their suppliers, the first "code of practice" for suppliers was published, which was revised in 1995 to include the then current GMP and requirements of ISO 9002:1994.

In 2001, again through collaboration with both packaging material suppliers and pharmaceutical customers, a significant revision was completed and PS 9000:2001 superseded the "code of practice" to become the recognized industry standard for the supply

of pharmaceutical packaging materials, which encompassed both ISO 9001:2000 and ISO 9004:2000. The reputation and success of PS 9000:2001 has been proven in that it has been widely applied and also used as a major source of reference in the development of other GMP standards at international level. In particular, the printing and pharmaceutical packaging industries are very familiar with PS 9000, being the recognized framework to which the pharmaceutical packaging supply chain works to ensure "fit for purpose" packaging components.

The new standard

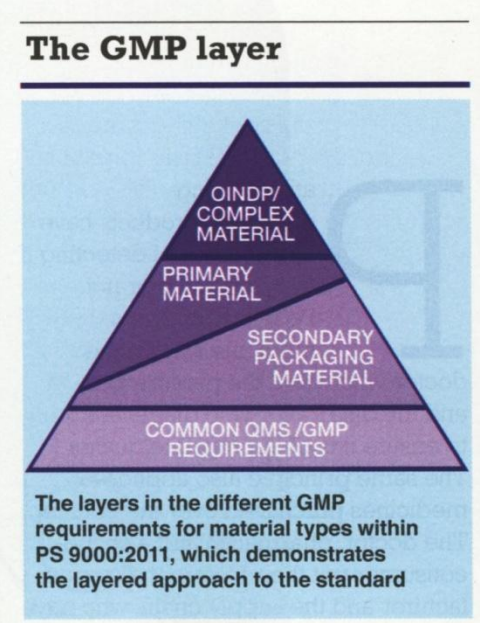
After a final consultation period earlier this year, the new PS 9000:2011 standard will be launched next month. Industry feedback during the development of the new standard welcomed the enhancements in subject matter such as "change control" and "supplier agreements" which encourage greater collaboration and a partnership approach between suppliers and customers throughout the supply chain.

Extending the scope of PS 9000 also provided the opportunity to review and embrace new GMP requirements or approaches set out in other standards,. e.g. ISO 15378 "Primary packaging materials for medicinal products", and EN 15823 "Braille on packaging for medicinal products" developing a "state of the art" publication for manufacturers and suppliers of all pharmaceutical packaging.

The consultation also concluded that the scope of PS 9000 should be extended to include additional GMP for Orally Inhaled and Nasal Drug Products (OINDP), i.e. products such as metered dose inhalers and nasal sprays, and to modernise the GMP requirements for secondary and primary packaging materials. This was a natural progression because the standard for OINDP developed by IPAC-RS had previously utilised PS 9000:2001 as its structure. The developers of the OINDP standard, IPAC-RS, agreed to collaborate in this revision, which all provided the dicinal products", with the intention of foundations for the evolution of the new standard.

PS 9000:2011 contains different GMP requirements for material types and is "layered" as follows:

- Global requirements - generic and Orally Inhaled and Nasal Drug Products applicable to all material types
- Specific requirements for secondary packing materials above the globa requirements
- Specific requirements for primary packing materials above the global requirements
- Detailed specific requirements for materials used in OINDP or for complex materials.



The layers in the different GMP requirements for material types within PS 9000:2011, which demonstrates the layered approach to the standard

Good Manufacturing Practice requires that manufacturers can demonstrate control of their processes and verify the quality of the packaging materials. To control the potential risks to patient health, suppliers must take into account all factors that could affect the quality of their products.

PS 9000:2011 not only details the requirements to attain the appropriate standard, but also provides the user with good sources of information and references for the development of their quality system, whether the product is artwork origination and approval, a carton, patient information leaflet, bottle or a complex mix of

components that make up a metered dose inhaler valve.

PS 9000:2011 encourages ongoing measures to ensure an effective, overall approach to product quality assurance and risk management, with additional referencing to the PQG publication *Supply Chain Risk Management,* Additionally, an annex to the document provides the user with guidance on how to implement and use risk management in a structured manner. The document also includes guidance on verification and validation requirements, which are specific topics, required when supplying the pharmaceutical industry and aimed to help define when to validate and what a suitable validation process would be.

To assist users of the PS 9000 standard, the document itself has been developed into an interactive PDF integrating both the requirements the supplier must comply with, and also guidance to assist the user in both the implementation and development of their quality systems.

Support

During development over the past two-and-a-half years, the PS 9000:2011 standard has been through a number of consultation phases across the industry, and now, with the incorporation of current technological developments and the latest approaches to good manufacturing practice, has become the leading certifiable standard in packaging supply for the pharmaceutical industry.

The standard has also been supported by the Medicines and Healthcare Regulatory Authority (MHRA) and includes a forward by Gerald Heddell, Director Inspection, Enforcement and Standards Division, MHRA.

Phil Butson, Chair of the PQG says:
"The new standard represents a significant development with additional useful content and clearer requirements. Working together with IPAC-RS has ensured additional applications are covered in a single standard.
"Making this document freely available to download will encourage further use of the standard by suppliers and users for the benefit of all those involved in the supply chain through to the patients."

Launch

The new PS 9000:2011 standard will be launched at the Royal Pharmaceutical Society of Great Britain in London on 14 September where attendees can see and hear how it will apply in practice, together with experiencing a unique standard, which has made use of current technology to deliver a user interface as an interactive standard.

The event brings together a team of high-profile speakers with a wealth of experience from the pharmaceutical industry, their suppliers, regulators (MHRA) and industry bodies (IPAC-RS). Discussion will focus on the updated requirements and guidance from the PS 9000:2011 standard as well as its applicability to both suppliers and the pharmaceutical industry in ensuring appropriate

Good Manufacturing Practice within the supply chain for packaging materials.

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