RISK MANAGEMENT, STERILE PHARMACEUTICAL PRODUCTS AND A POST-BREXIT UK PHARMA INDUSTRY

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Sterile products are designed to be injected or infused directly into the bloodstream, bypassing the body's natural defense mechanisms. Both doctors and patients must be assured they're sterile and free from endotoxins and other harmful elements.

The EudraLex Good Manufacturing Practice (GMP) Volume 4 Annex 1 is the newest guidance for the pharmaceutical industry in the EU. It lays out the minimum GMP standards expected to work in a sterile pharmaceutical manufacturing environment.

"It's all about the level of risk you're prepared to accept, alongside any perceived benefit," said NSF International Pharmaceutical Services, Vice President John Johnson. "The onus is on the manufacturer to demonstrably prove that the product has the required level of sterility assurance, not for others to prove that it is contaminated.

"The contamination control strategy forces the industry to become much more transparent about the risks that it is aware of and much more engaged and proactive in assessing and scoring those risks. It requires the license holder to be forensic and transparent in identifying those risks, in assessing their likely impact and putting in place mitigation plans for those risks deemed unacceptable."

The process of documenting those risks – using science, hard data and logic – will be a critical document to be offered up at regulatory GMP inspections and client audits. This level of transparency and the responsibility to find all known or possible risks throughout the facility is almost unprecedented.

GMP requirements detailed in ICH Q9, Quality Risk Management have been guiding manufacturers in how to identify risk and prioritize the areas that may be most detrimental to the quality of their products.

CONTAMINATION CONTROL STRATEGIES AND NEW EU GUIDANCE

Just as society sees risk differently now than it did 25 years ago – as witnessed by regulation on seatbelts, car design and smoking in public places – the pharma industry is also compelled to consider risk differently.

Processes which were once industry norms are now potentially seen as major GMP deficiencies.

With ICH Q9 and the need for a contamination control strategy, the onus is on the industry to be even more active in identifying risk and tackling it head on, especially in legacy facilities.

"The big deal is that the contamination control strategy is an open book," said Johnson. "Previously, the onus was on the inspector to find infringements during a relatively short GMP inspection. Due to the fact that every inspection can only ever be a sampling exercise, there was a good chance that they would miss things.

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"That's completely changed; the responsibility is now on the license holder to assess all of the risks with their combined expertise on site, codifying them, assessing them, evaluating them and ultimately applying some degree of corrective and preventive action."

With Brexit looming, Johnson believes that pharmaceutical manufacturers need to take this self-starting attitude to risk management and apply it to the UK's departure from the EU.

THE IMPACT OF BREXIT ON PHARMACEUTICAL MANUFACTURERS

Companies who manage risk best are those that face reality, are willing to accept uncomfortable truths and learn quickly and adapt their approach as market requirements change. To do that, the industry needs some clear guidance and instruction on the new paradigms.

Whichever way an individual sees Brexit, there has been a huge lack of information, surety and purpose. Without this, society and industry will always use creative pessimism, what ifs and worst-case scenarios to set the new norms.

Unfortunately, this approach can often be a huge distraction for business, with unpredicted costs and ambiguity. Decisions made with creative pessimism are often knee jerk and unsustainable, tactical rather than being strategic. They can thus appear counterintuitive to company values and overall mission.

NSF's role as leaders in the field of risk management is to help pharmaceutical organizations steer a justifiable route through the uncertainty. The organization aims to help its clients be proportionate and precise in defining what constitutes a true risk, compared to an acceptable and minor distraction.

NSF consultants can also provide advice in the fields of contamination control and quality assurance. Guidance, auditing and coaching programs can help to equip pharmaceutical organizations for the uncertain future ahead, making sure their growth plans are not disrupted by changes to the business environment.

ABOUT JOHN JOHNSON

John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms.

For more information, contact **pharmamail@nsf.org** or visit **www.nsfpharma.org**

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NSF INTERNATIONAL | PHARMACEUTICAL SERVICES

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 I **E** pharmamail@nsf.org

789 N. Dixboro Road, Ann Arbor, MI 48105, USA
T +1 (202) 822 1850 I **E** healthsciences@nsf.org

www.nsf.org I **www.nsfpharma.org** I Follow us on LinkedIn & Twitter