Pharmaceutical Quality Assurance & Control

The world of pharmaceutical development and manufacture is having to change its culture and practice to meet the opening global market. Outsourcing, global sourcing and international inspections are becoming a common occurrence and international pharma companies need to differentiate by having consistent, world-class GXP compliance systems that meet the demands of many stakeholders and inspection authorities. The demand for consistent Quality Management Systems is becoming a requirement, not an option.

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QUALITY ASSURANCE OF PHARMACEUTICALS

The quality of pharmaceuticals has been a concern of the World Health Organization (WHO) since its inception. The setting of global standards is requested in Article 2 of the WHO Constitution, which cites as one of the Organization's functions that it should "develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products." Every government allocates a substantial proportion of its total health budget to medicines. This proportion tends to be greatest in developing countries, where it may exceed 40%.

Without assurance that these medicines are relevant to priority health needs and that they meet acceptable standards of quality, safety and efficacy, any health service is evidently compromised. In developing countries considerable administrative and technical effort is directed to ensuring that patients receive effective medicines of good quality. It is crucial to the objective of health for all that a reliable system of medicines control be brought within the reach of every country. The supply of essential medicines of good quality was identified as one of the prerequisites for the delivery of health care at the International Conference on Primary Health Care in Alma-Ata in 1978. Similarly, the Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985, and WHO's Revised Drug Strategy, adopted by the World Health Assembly in May 1986, identified the effective functioning of national drug regulation and control systems as the only means to assure safety and quality of medicines.

Yet the World Health Assembly continues to express great concern about the quality, safety and efficacy of medicines, particularly those products or active pharmaceutical substances imported into, or produced in, developing countries. In recent years counterfeit products have infiltrated certain markets in disquieting proportions. Since the founding of WHO, the World Health Assembly has adopted many resolutions requesting the Organization to develop international standards, recommendations and instruments to assure the quality of medicines, whether produced and traded nationally or internationally even though they were made several years ago, are still valid.

Thus far, however, most have been available only as separate sets of recommendations contained in annexes to various WHO Technical Reports. The recommendations are essential to all concerned with the quality assurance of medicines, but separate publications over a period of years has made it difficult to recognize them as complementary parts of a comprehensive system of quality assurance.

Protect your supply chain: Maximize Quality Across the Organization

VULNERABILITIES IN THE SUPPLY CHAIN

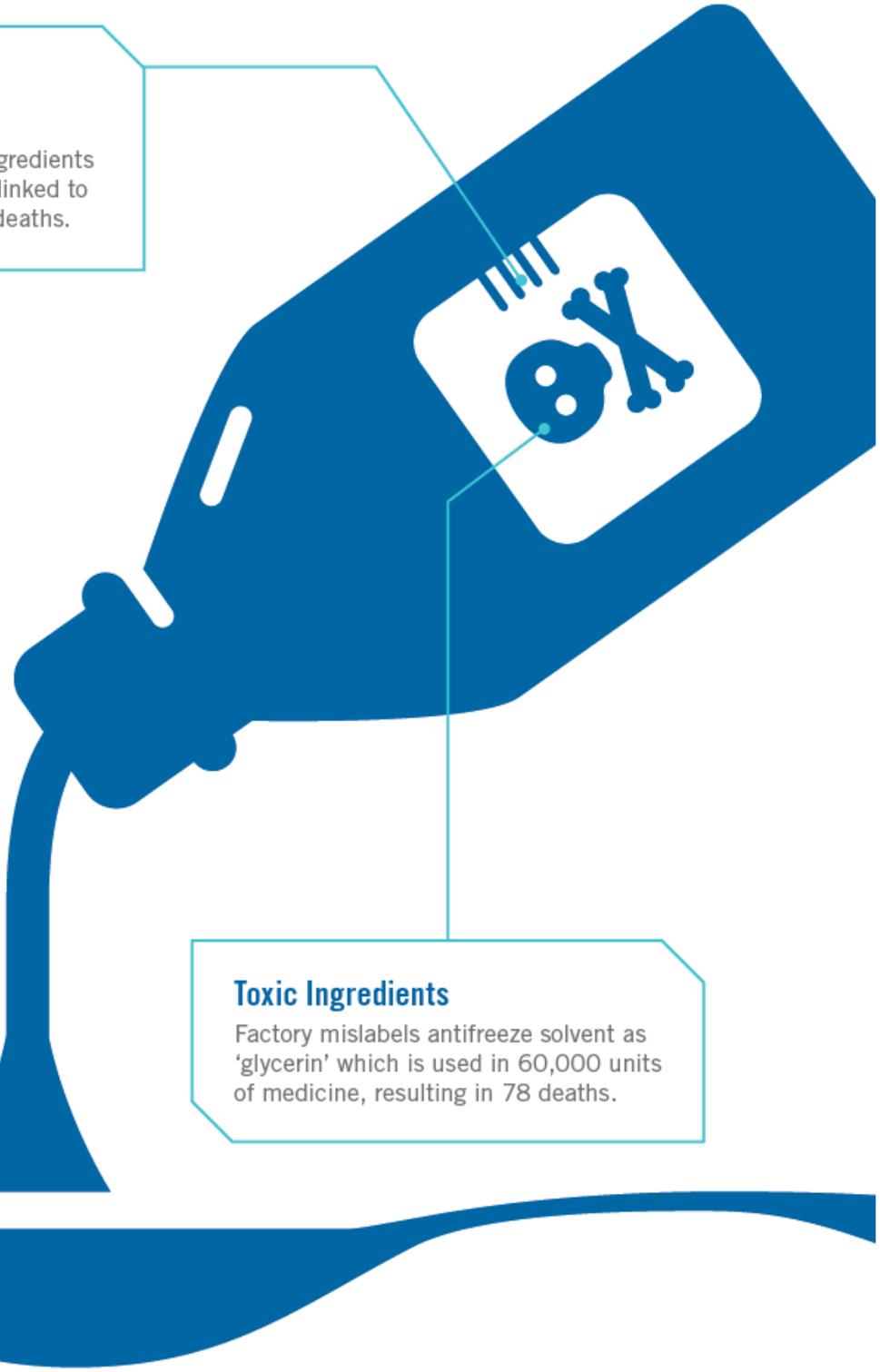
Counterfeits have entered legitimate pharmaceutical supply chains at nearly every step.

False Labeling of Pharmaceutical Ingredients

Broker falsely labels low-cost active ingredients as if from FDA-approved facility; later linked to 1,974 adverse reactions including 49 deaths.

Counterfeits Sold to Wholesalers

Florida criminals relabel low-dose anemia drug as a higher-strength product; passes via intermediaries to chain drugstore which sells counterfeit medicines to as many as 90,000 patients.



Adulterated Raw Materials

Supplier uses a cheaper synthetic chemical for blood thinner Heparin. Result: possible cause of 3-9 deaths.

Adulteration by Pharmacies

German pharmacist charged with handling $2.16 million in counterfeit medications for impotency, bodybuilding products, painkillers, antibiotics, and cancer drugs.

Toxic Ingredients

Factory mislabels antifreeze solvent as 'glycerin' which is used in 60,000 units of medicine, resulting in 78 deaths.

REDUCE THE RISK: TOP PRACTICES

1. Foster greater cooperation, coordination, and accountability among all participants.
2. Increase information sharing to strengthen supply-chain integrity.
3. Work collaboratively with government authorities to support product safety and quality.

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OVERVIEW

The world of pharmaceutical development and manufacture is having to change its culture and practice to meet the opening global market. Outsourcing, global sourcing and international inspections are becoming a common occurrence and international pharma companies need to differentiate by having consistent, world-class GXP compliance systems that meet the demands of many stakeholders and inspection authorities. The demand for consistent Quality Management Systems is becoming a requirement, not an option. Delegates will therefore learn the core elements of an internationally recognized GMP QMS, know the core legislation elements of key markets and be able to author and implement a fit-for-purposeGMPQMSand compliance system to meet the international market, with the aim of becoming 'inspection-ready'. Because the pharmaceutical industry has traditionally focused upon the application of Good Manufacturing Practice (GMP), it has been slow to consider the potential benefits to be gained by implementing an EN ISO 9001Quality Management System (QMS). Over the last few years the global pharmaceutical market has undergone significant change, forcing pharmaceutical companies, more than ever before, to focus on customer needs and upon their own internal efficiency in order to continue to compete effectively

LEARNING OBJECTIVES

- To be effective the QMS should have the visible and ongoing support of top management.
- To fully benefit the company the QMS should involve all staff whose activities influence quality, have a clear and unambiguous continuous improvement focus, and incorporate relevant, realistic performance measures with emphasis on reducing failure costs, and satisfying (internal and external) customer needs.

COURSE LEADER

Peter Deegan is an experienced Pharma Quality Management Systems professional, with over 25 years GMP, audit, training, ISO9001 and Regulatory Affairs experience. Peter specialises in international QMS, with in-depth knowledge of Japan, India, East Asia and Middle East. Peter, a UK Chemistry graduate, started his career working for a small UK generics solid-dose Pharma, where he gained significant experience in laboratory QC and hands-on manufacturing Quality Assurance. He joined ICI Pharmaceuticals (now called AstraZeneca) in 1992, where he held Senior QA Officer roles in both quality systems and parenteral manufacturing. He received a post-graduate Diploma in Pharmaceutical Quality Assurance with Distinction in 1995, the same year that he achieved European Qualified Person status; he gained his MBA in 2003.

Peter later moved to R&D in AstraZeneca, where he held positions in Regulatory Affairs, Training Management and, finally, as Global Head of QA for Regulatory Compliance in R&D, where he regularly conducted audits world-wide and led the QA due diligence and on-boarding programme for a major outsourcing programme to India.

Peter is a world-class trainer, with many years of hands-on experience in GMP compliance, inspections and Pharmaceutical regulations. He brings many real-world examples of how to implement a 21st-century compliance system to Pharma. He is an expert in document management systems and advises companies on how to write SOPs that engage and motivate staff to achieve compliance more effectively.

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