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Good Practice Guide: Management of Engineering Standards

ISPE has published a new Good Practice Guide: Critical Utilities GMP Compliance—How to Be Compliant and Ready to Prove It. Written and reviewed by a team of experts from around the world, the guide is the first of its kind in the industry. Team co-leads Nik Krpan and Rod Freeman talked with Pharmaceutical Engineering® about the importance of critical utilities and the benefits of the new guide.

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December 2019. The ISPE Good Practice Guide: HVAC and Process Equipment Air Filters aims to be a valuable reference on the selection, application, specification, testing, and operation and maintenance of filters in the pharmaceutical industry. This Guide is intended to be used

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ISPE announced the release of its latest guide, ISPE Good Practice Guide: Critical Utilities GMP Compliance – How to Be Compliant and Ready to Prove It.The Guide was cultivated by leading experts to help pharmaceutical organizations achieve and maintain their critical utility systems in a state of control, and then be able to efficiently

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Entitled ISPE Good Practice Guide: Critical Utilities GMP Compliance—How to Be Compliant and Ready to Prove It, the guide also helps to efficiently show that the critical

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Approach to Compliant GxP Computerized Systems provides pragmatic and practical industry guidance that aims to achieve compliant computerized systems that are fit for intended use in an efficient and effective manner, while also enabling innovation and technological advances.

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Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture

of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook

describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

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