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ISPE. The 2nd edition of the ISPE Good

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Practice Guide: Maintenance is currently under revision and the team leaders, Constantino Rodriguez (formerly Outlook Therapeutics) and George Wittman (JLL Chicago), are looking for additional volunteers to assist with specific chapters for the update. They are looking for subject matter experts to draft and/or edit content

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for the following topics as they relate to
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compliance of maintenance operations in a regulated industry. Covering current and established practices, this guide helps achieve technical and regulatory accuracy and cost-effective compliance in a new or an existing maintenance program for effective strategy and efficiency.

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This Guide brings a wealth of information on GEPs and provides benchmarking tools of current company practices against what is considered industry good practice. The ASTM standard (E2500) builds on the concepts of GEPs and has substantial

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implications for reductions in cost and time for pharmaceutical capital investment projects.

~~Good Practice Guide: Good Engineering Practice~~

This course leverages the content and templates from the ISPE Good Practice

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Guide: Maintenance to provide the tools for the development, implementation, and execution of cost-effective compliance for new or existing maintenance programs in a pharmaceutical manufacturing environment.

~~Maintenance: Reliability, Engineering and~~

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It helps to develop, establish, document, implement, maintain and improve industry good practice for product requiring controlled cold conditions. The Guide is intended to provide practical guidance to assist in the specification, design, commissioning and verification of the fixed

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and passive systems within the cold chain.

~~Good Practice Guide: Cold Chain Management~~

The ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC) provides designers and project teams with suggestions to help determine the user

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requirements and the functional design that define the facility's objectives. It also provides options to be considered in creating a design that has low lifecycle cost and is sustainable.

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Good Engineering Practice documentation standards; The intent of this revision to the Guide is to help the pharmaceutical industry simplify and improve the C&Q process by bringing the “ best of the best ” together into one document. This Guide also combines concepts from regulatory guidances (e.g., from EMA, FDA, ISO).

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~~Baseline Guide Volume 5: Commissioning
and Qualification ...~~

Benefits Provided by the ISPE Good
Practice Guide: Controlled Temperature
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an increased regulatory interest in cold chain
driven by the growing number of products

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requiring controlled temperature shipping and storage, the complexity of the distribution network for the products, and governmental requirements for distribution of vaccines.

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provides designers and the project team with suggestions to help determine the user requirements and the functional design that define the facility's objectives. It also provides options to be considered in creating a design that has low lifecycle cost and which is sustainable.

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Facility Project Management in the
Regulated Pharmaceutical Industry (T26)
Overview. This training course aims to
deliver more than the usual project basics
and will develop the concept of the project
lifecycle from initiation through to delivery

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of business benefits, providing tools to
manage all project resources.

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

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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

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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,

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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.

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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

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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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Dietary Supplement GMP is a one-stop "how-to" road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture, packaging, and holding of dietary supplement products. The recent regulations, outlining broad goals, intentionally avoid specifics to allow for

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future technological advances—leaving implementation to the discretion of each firm. Given this latitude and flexibility, this new resource is an essential source of workable and practical suggestions on ways the industry can best meet the goals. Based on broad experience with GMP compliance techniques worked out over the years in the

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food, drug, and medical device industries, it is a must-have guide for all DS companies, especially the many smaller firms for whom this is new territory. Dietary Supplement GMP provides: a practical guide in easy to understand language to help navigate through the requirements for systems covering process and quality control

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suggestions and practical recommendations
on "how-to" achieve full compliance
explanation of the FDA ' s role regarding
inspection, enforcement, recall/seizure of
products and prosecution Dietary
Supplement Good Manufacturing Practices
(GMP) covers: Personnel Plants and
Grounds Equipment and Utensils Sanitation

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of Buildings and Equipment Quality
Assurance and Laboratory Operations The
Quality Control Unit Production and
Process Controls

This GAMP Good Practice Guide: A Risk-

Page 47/51

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Based Approach to GxP Process Control Systems is a revision of the GAMP Good Practice Guide: Validation of Process Control Systems. It provides guidance and examples on the application of the principles and framework of GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems to a wide range of systems, from

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basic instruments to large, complex, distributed control systems. This Guide aims to achieve process control systems that are fit for intended use and compliant with applicable regulations; providing recommended good practice based on a life cycle approach for the development, maintenance, and management of process

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control systems. The Guide applies science-based Quality Risk Management, as described in ICH Q9 and GAMP 5. It describes the system life cycle from concept to retirement, providing a high level overview of the approach together with guidance on how activities might be scaled based on risk to product quality, system

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novelty, and complexity as well as other project specific factors.

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