Gamp Good Practice Guide

Good automated manufacturing practice

pharmaceutical industry. More specifically, the ISPE's guide The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical

GAMP is both a technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE [1]) and a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry. More specifically, the ISPE's guide The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture describes a set of principles and procedures that help ensure that pharmaceutical products have the required quality. One of the core principles of GAMP is that quality cannot be tested into a batch of product but must be built into each stage of the manufacturing process. As a result, GAMP covers all aspects of production; from the raw materials, facility and equipment to the training and hygiene of staff. Standard operating...

Good practice

product meets its required specifications and quality ISPE

GAMP® Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Computerized - A good practice is a procedure or set of procedures that are prescribed or accepted as being suitable or effective within a given professional or commercial setting. They are used in quality guidelines and regulations, including the pharmaceutical and food industries, for example good agricultural practice (GAP) (see more examples below).

In general, GxP is a placeholder abbreviation for the good practice within a particular field or fields, where the "x" can be substituted for the field(s) in question. GxP can also be used to refer to collections of quality guidelines.

To denote the current good practice, a "c" or "C" is sometimes added to the front of the initialism (cGxP), which may hint that any good practice may be subject to future change. For example, "current good manufacturing practice...

Good engineering practice

Pharmaceutical Inspection Co-operation Scheme (PIC/S) "Good Practice Guide: Good Engineering Practice". ISPE | International Society for Pharmaceutical Engineering

Good engineering practice (GEP) is engineering and technical activities that ensure that a company manufactures products of the required quality as expected (e.g., by the relevant regulatory authorities). Good engineering practices are to ensure that the development and/or manufacturing effort consistently generates deliverables that support the requirements for qualification or validation. Good engineering practices are applied to all industries that require engineering.

Good manufacturing practice

Corrective and preventive action (CAPA) EudraLex Food safety Good automated manufacturing practice (GAMP) in the pharmaceutical industry Site Master File Washdown

Current good manufacturing practices (cGMP) are those conforming to the guidelines recommended by relevant agencies. Those agencies control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their

intended use.

The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user. Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented...

Validation master plan

system associated with a validation project based on a risk assessment. The GAMP 5 standard recommends an approach to the creation of the plan. Topics commonly

A Validation Master Plan, also referred to as "VMP", outlines the principles involved in the qualification of a facility, defining the areas and systems to be validated, and provides a written program for achieving and maintaining a qualified drug manufacturing facility. A VMP is the foundation for the validation program and should include process validation, facility and utility qualification and validation, equipment qualification, cleaning and computer validation. It is a key document in the GMP (Good manufacturing practice) regulated pharmaceutical industry as it drives a structured approach to validation projects.

In the US, Food and Drug Administration inspectors often look at VMPs during audits to see whether or not a facility's validation strategy is well thought-out and organized....

Validation (drug manufacture)

evaluation of manufacturer regulatory compliance as well. Good Automated Manufacturing Practice (GAMP) Verification and Validation Pharmaceutical Inspection

In drug manufacture, validation is a documented process to ensure a product meets its required specifications and quality. The process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages. In the pharmaceutical industry, it is very important that in addition to final testing and compliance of products, it is also assured that the process will consistently produce the expected results. The desired results are established in terms of specifications for outcome of the process. Qualification of systems and equipment is therefore a part of the process of validation. Validation is a requirement of food, drug and pharmaceutical regulating agencies such as the US FDA...

Halliwick

Sciences. pp 1106-1116 (Halliwick Concept). ISBN 9780702053030. Lambeck, J and Gamper U. 2011. The Halliwick Concept. In: Becker, BE and Cole, AJ and (eds). 2011

The Halliwick Concept focuses on biophysical principles of motor control in water, in particular developing sense of balance (equilibrioception) and core stability. The Halliwick Concept recognises the benefits that can be derived from activities in water, and sets out the fundamentals necessary for teaching and learning in this environment. The Halliwick Ten-Point-Programme implements the concept in a progressive programme of mental adjustment, disengagement, and development of motor control, with an emphasis on rotational control, and applies the programme to teach physically disabled people balance control, swimming, and independence. Halliwick Aquatic Therapy (also known as Water Specific Therapy, WST), implements the concept in patient-specific aquatic therapy for application in rehabilitation...

Shock (circulatory)

1549–57. doi:10.1213/ANE.0000000000002451. PMID 28930937. S2CID 39310937. Gamper, Gunnar; Havel, Christof; Arrich, Jasmin; Losert, Heidrun; Pace, Nathan

Shock is the state of insufficient blood flow to the tissues of the body as a result of problems with the circulatory system. Initial symptoms of shock may include weakness, elevated heart rate, irregular breathing, sweating, anxiety, and increased thirst. This may be followed by confusion, unconsciousness, or cardiac arrest, as complications worsen.

Shock is divided into four main types based on the underlying cause: hypovolemic, cardiogenic, obstructive, and distributive shock. Hypovolemic shock, also known as low volume shock, may be from bleeding, diarrhea, or vomiting. Cardiogenic shock may be due to a heart attack or cardiac contusion. Obstructive shock may be due to cardiac tamponade or a tension pneumothorax. Distributive shock may be due to sepsis, anaphylaxis, injury to the upper…

List of Dickensian characters

Harris, Mrs Imaginary friend of Sairey Gamp who uses Mrs Harris's invented quotes to establish Mrs Gamp's good reputation in Martin Chuzzlewit. Harthouse

This is a list of fictional characters in the works of Charles Dickens.

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Charles Dickens

life of their own outside his books. "Gamp" became a slang expression for an umbrella from the character Mrs Gamp, and "Pickwickian", "Pecksniffian" and

Charles John Huffam Dickens (; 7 February 1812 – 9 June 1870) was an English novelist, journalist, short story writer and social critic. He created some of literature's best-known fictional characters, and is regarded by many as the greatest novelist of the Victorian era. His works enjoyed unprecedented popularity during his lifetime and, by the 20th century,

critics and scholars had recognised him as a literary genius. His novels and short stories are widely read today.

Born in Portsmouth, Dickens left school at age 12 to work in a boot-blacking factory when his father John was incarcerated in a debtors' prison. After three years, he returned to school before beginning his literary career as a journalist. Dickens edited a weekly journal for 20 years; wrote 15 novels, five novellas, hundreds...