

bGxP® and Human Error (3 days)

Overview

There is no longer any room for complacency in our industry! With increasing complexity within the drug supply chain, there is an ever increasing exposure to non-compliance for those organisations that assume that ‘what they’ve always done before’ will be sufficient. Increasing concerns are forcing the regulatory bodies to step up their activity and organisations need to be culturally prepared not just checklist approved. Simply meeting the audit requirements on a particular day, at a particular time often needs preparation and planning but shouldn’t our industry be audit ready, 24 hours, 7 days a week, knowing that at any stage prior to or after the audit the expectation is that we will perform consistently, producing safe and effective product 100% of the time? But do we retain that heightened audit awareness?

Imagine if 50 employees enter a toilet and only 49 wash their hands on leaving. If that one person was the first to enter& leave then they have just contaminated the other 49, who remain totally unaware that they are now contaminated. In a GMP environment the question we would ask is simple, “why didn’t they wash their hands?”

In a heavily regulated and high risk industry like ours, organisational culture plays an important and crucial role in the overall performance of the business. The values and beliefs of those responsible for managing and operating within the industry have to be in alignment with those enforcing the rules and regulations. If it differs then we have a problem! The concept of bGxP® has developed over several years, partly from Behavioural Safety and from P Crosby’s 14 step Quality improvement programme, into a programme designed to assess and review the compliance culture within the business, identify and implement appropriate changes and then to review and measure improvements. With various tools available to the bGxP® coach, improvements can be facilitated throughout with clear measurable improvements in performance and employee behaviour. bGxP® is primarily a programme designed to improve compliance, however with the various elements of Lean, Cost of Quality and behavioural change initiatives incorporated throughout, the expectation is that most organisations would also achieve significant productivity gains.

Objectives

On completion, participants will be able to:

- Assess the risks of non-compliance within their operation
- Understand the concept of behavioural GMP
- Introduce elements of the bGxP® programme back in the workplace
- Apply the concept of LEAN thinking in managing their compliance
- Understand the various models of human error and how they apply to their own culture
- Carry out investigations involving human error with more precision and effectiveness
- Identify strategies for reducing and/or eliminating error
- Provide Coaching in behavioural GMP techniques
- Understand the role of job profiles and psychometrics in assessing human factor risk



TKnP

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Contents

- Review of cGMP (Changes in the industry, ICH Q7-Q10)
- Introducing the concept of bGxP® and what it can achieve
- Auditing the business risk (Job Profiling and Psychometrics and evaluating cultural risk)
- Managing Change and the bGxP® culture change programme
- bGxP® metrics for change and improvement
- Drivers for bGxP® Change (The PIMS model)
- Models of Human Error (Sequence of events, Epidemiological, Systemic)
- Principles of Error management
- Causes of error and strategies for reducing/eliminating risk
- COST role profiling
- Behavioural Change models
- bGxP® Coaching

Format

Led by an instructor with over 15 years' experience of cultural change management at senior level in the industry, the course consists of a lively mix of presentations, workshops, group exercises and discussions. Anecdotes and personal experiences will be shared to help delegates apply the knowledge back in the workplace.

Attendees

This course is designed for anyone that is serious about influencing and changing the compliance culture within their organization.

Course Materials

Copies of all presentation slides, notes and handouts will be provided. On completion of the course, each delegate will be presented with a certificate.

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