



"The great majority of reported defective medicinal products has resulted from human error or carelessness, not from failures in technology".

UK 'Orange Guide' - 2007

Behavioural GMP (bGMP) is the systematic application of psychological research on human behaviour to the problems of GMP in the workplace.

This programme is based upon the concepts of influencing and changing human behaviours, to create sustainable compliance and quality which isn't just 'right first time' but **'right every time'**.

bGMP is a way of life in the pharmaceutical industry



Behavioural GMP

GMP

“A set of Rules designed to ensure that employees comply with the strict requirements of pharmaceutical manufacturing.”

Defined by a company's SOP set.

Communicated widely but managed badly!



When GMP Fails!

“Quality is fitness for Purpose”

- * We can only test samples
- * We cannot test everything
- * Patients may not detect that anything is wrong

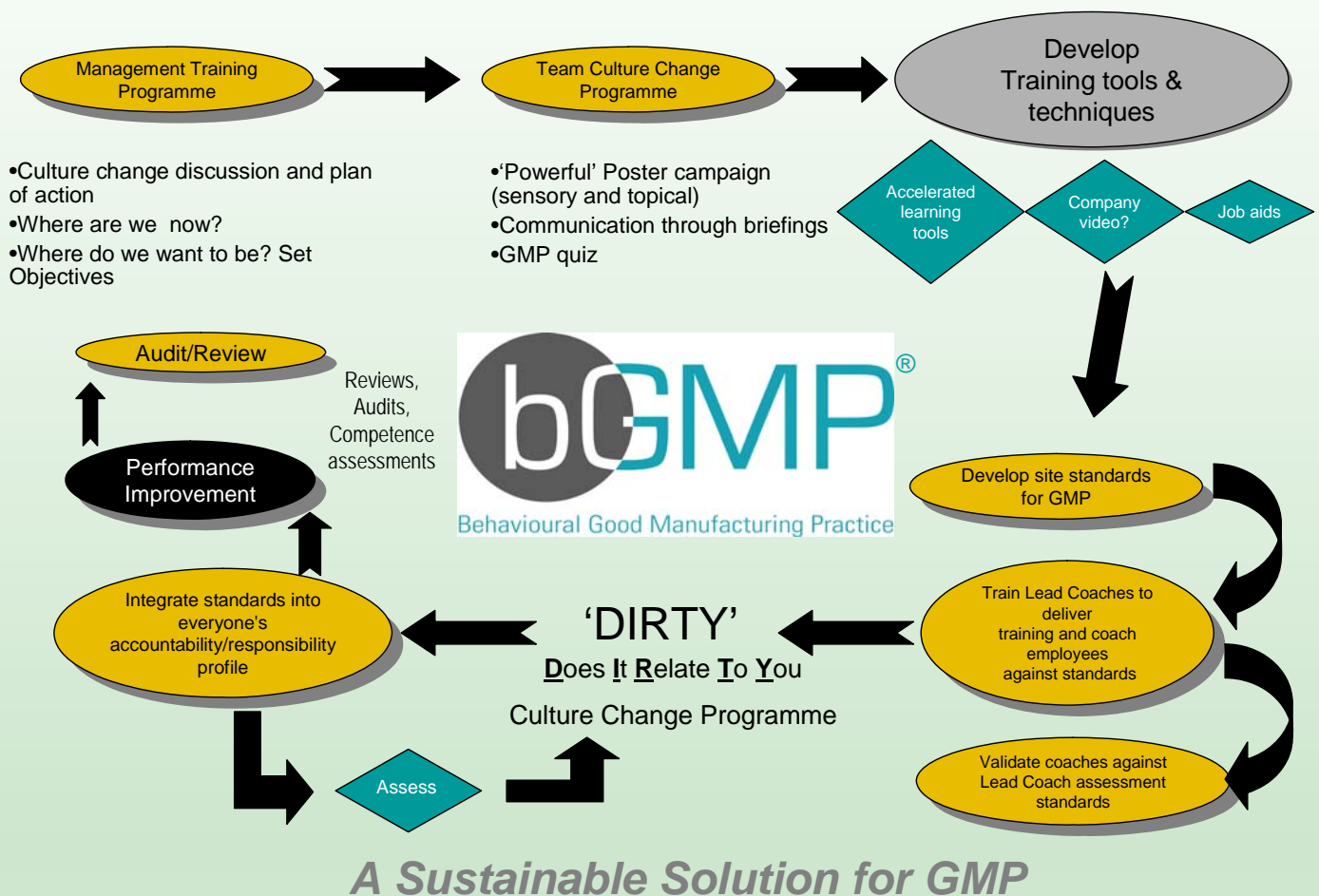
Mistakes can Kill!

What is bGMP?

“A holistic approach to Quality, that ensures a level of expertise and awareness which will define standards, maintain compliance and sustain improvements.”

bGMP is “a way of life in the pharmaceutical industry.”

Behavioural GMP

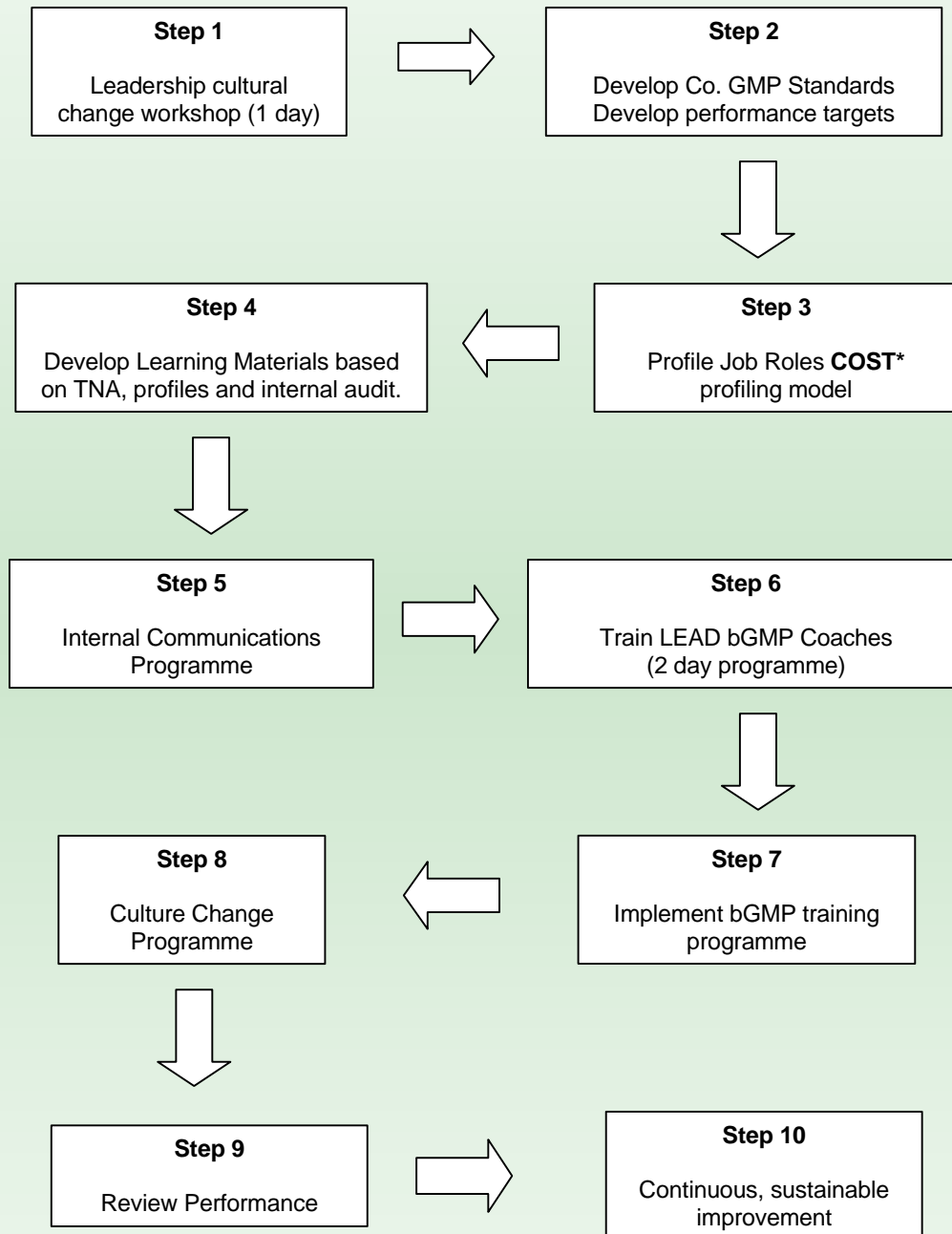


bGMP Overview

- bGMP is a Sustainable Quality Programme
- It will develop a performance culture
- It includes training for Managers and bGMP Lead Coaches
- Current metrics for Quality and Behaviour are identified
- It will introduce a new style of leadership "The Balanced Leader"
- It will facilitate the development of company Quality Standards
- It will include the delivery of Team Culture Change workshops
- Regular audits and communication of results will form part of the feedback process

Behavioural Good Manufacturing Practice

Ten Steps to bGMP



***COST** = Core – Optional – Specific – Targeted (skills)

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