

Workshop & Report

- problem clarification by Eltronic Pharma Engineering



A PRELIMINARY INVESTIGATION
OF A PHARMACEUTICAL ISSUE

Eltronic

PHARMA ENGINEERING

A preliminary assessment of an issue

Could your GMP setup benefit from a gap analysis, is your production in need of an inspection or would your flow of documents profit from an impartial assessment?

The extent of pharmaceutical issues can be difficult to grasp, making the estimation of a project impossible. Shedding extra light on the issue before turning it into a project is beneficial as it eliminates many unknowns. A potential project will thereby become more focused, saving you time and resources.

At Eltronic Pharma Engineering, we assist you in assessing the rootcause and extent of your issue with our one-day workshop.

We bring our pharmaceutical consultants to the workshop. They will investigate the issue together with relevant personal of your choice. The number of consultants we bring depends on the nature and extent of the issue.

During the workshop we investigate your issue and prepare a report with recommendations for further improvements. The workshop provides you with actionable insights from a documented investigation performed by unbiased experts.

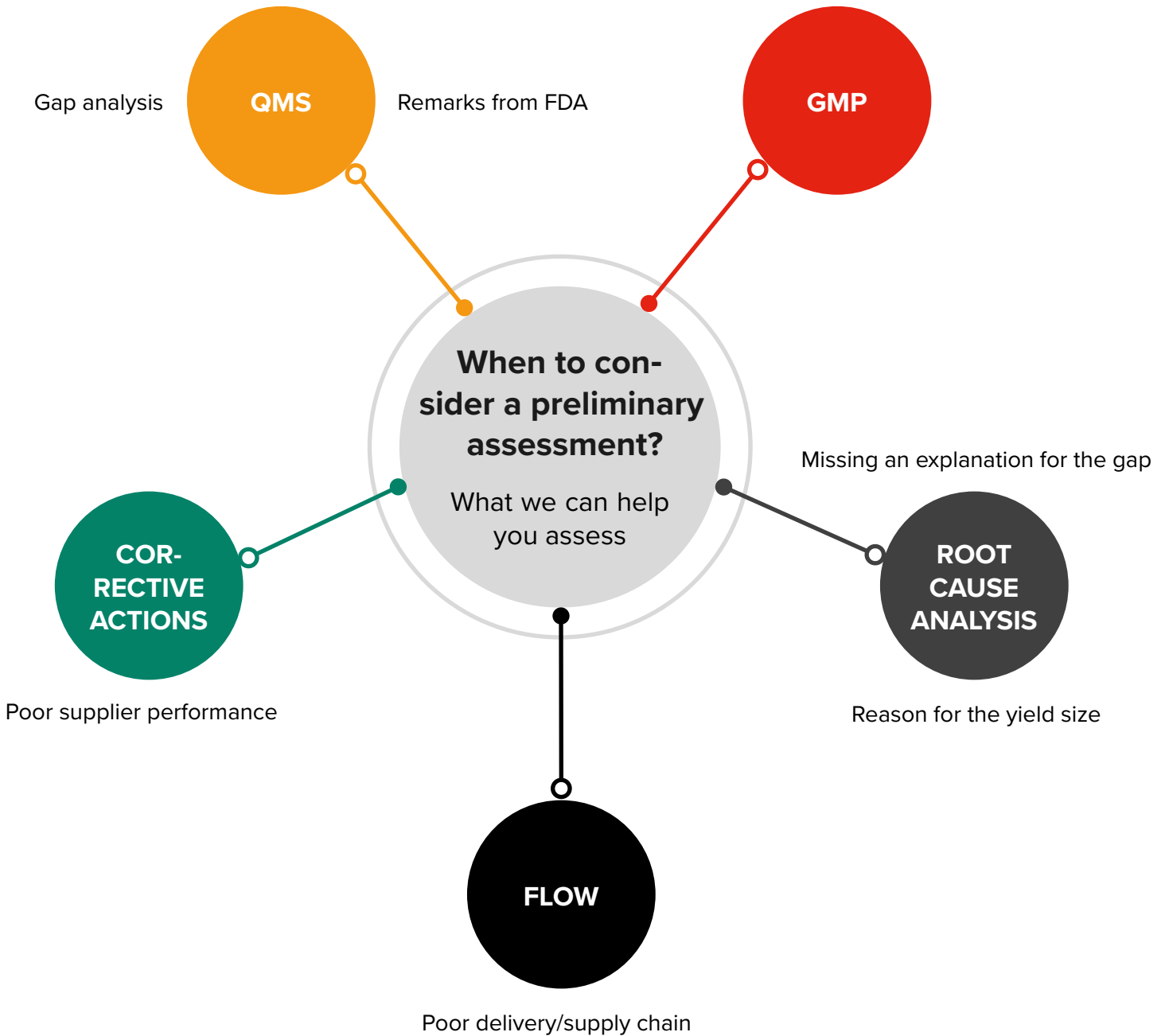
One-day assessment workshop



WORKSHOP EXAMPLE

Half-day workshop with 2 participating consultants + half-day report preparation

Problem clarification



Our main competences

- ✓ GMP
- ✓ Compliance
- ✓ Documentation
- ✓ §39
- ✓ Compliance

- ✓ Gap analysis
- ✓ Quality management
- ✓ Operation excellence
- ✓ Audit/inspections
- ✓ Risk management

- ✓ QA/QC
- ✓ GAMP V
- ✓ QMS
- ✓ Good documentation practice

A Holistic Project Approach

No matter what type of project we take on at Eltronic Pharma Engineering, we use a holistic project approach.

The approach integrates aspects from 3 main areas - Quality Management, Change Management and Lean Management.

All members of our team have extensive experience working with all 3 areas. Using the approach, we are able to ensure that:

- + **Quality Management**
All requirements are met - but redundant requirements are eliminated. Focus on “need-to-have” instead of “nice-to-have”.
- + **Change Management**
Changes are implemented at all relevant levels of the organisation.
- + **Lean Management**
Projects are carried out as efficiently as possible both with regard to time, cost and quality.



About Eltronic Pharma Engineering

Eltronic Pharma Engineering is a team of highly specialized and experienced GMP consultants as well as IT and automation specialists. We help our customers with all aspects of quality management, GMP compliance and processes.

www.eltronic.dk/markets/life-sciences

Eltronic Pharma Engineering is a part of Eltronic A/S - an engineering company focused on increasing the productivity, flexibility and efficiency of its customer's business.

Eltronic employs more than 260 highly professional engineers and technicians covering competencies within a wide range of disciplines.

Contact Information

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