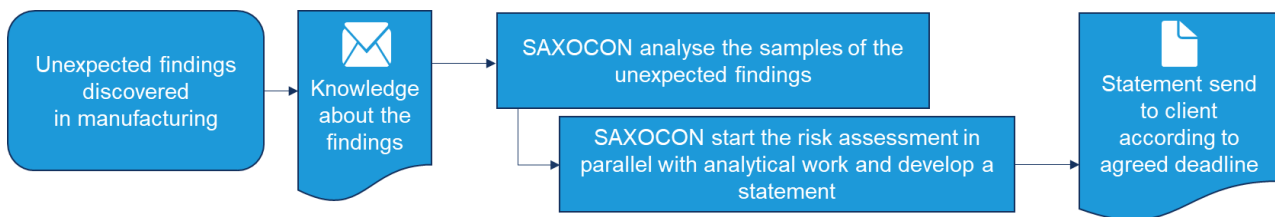


# Unexpected particulate matter findings

Sudden unexpected findings of particulate matter in, or in contact with, drug products are common in pharmaceutical production facilities. Good Manufacturing Practice (GMP) and proper risk management of product quality requires identifying the root-cause and evaluating the impact of findings on product safety. This knowledge can be crucial for deciding whether to release or recall affected product batches.

A predefined service level agreement (SLA) with SAXOCON provides a fast-track process with everything you need to analyse and evaluate the impact of deviations or non-conformances:



- Optimal stacking of activities ensures a 2-3 weeks lead time from discovery to toxicological risk assessment.
- SAXOCON has the expertise and laboratory capabilities to quickly and accurately identify the root-cause of any findings
- Expert advice in sampling and risk mitigation
- Toxicological risk assessment

## Why choose us?

SAXOCON services for manufacture of pharmaceutical products give you access to:

- Extensive experience in state-of-the-art safety assessment of pharmaceutical products according to international standards and regulatory guidelines
- A multidisciplinary team of highly skilled scientists and experts
- Extensive expertise in the measurement and characterisation of materials incl. nanomaterials

## Delivery

SAXOCON compiles all necessary results and documents them in a toxicological risk statement.