

Out-of-Specification (OOS) | APP-P0038 Overview

OOS | APP-P0038 Overview

Developed for
companies in
the following
industries:



BIOTECH



MED DEVICE



PHARMA



R&D



VIRTUAL

ABOUT THIS QM APP

"Out-of-specifications (OOS) arise when product owners received manufactured goods not in accordance with their negotiated Quality Agreements. This OOS/OOT business process is intended for virtual companies."

--Brian Graeff, Head of the Quality & Best Practices Unit, SOLABS

HIGHLIGHTS

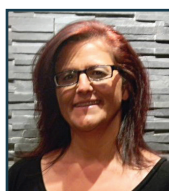
- The process starts with the initiation of a Lab Investigation
- At Steps 2, as the Investigation Conclusion is reached, both departmental management approval (Step 3) and a QA review (Step 4) are required
- The Manufacturing Investigation begins Phase II, in this case with the contract laboratory
- Extension Requests provide flexibility, and QA has a final approval
- Additional Testing provisions allow for further task steps for unresolved items
- The process closes with an interpretation of the investigation results and the release decision that follows

AUTHORS



Brian Graeff, Head of the Quality & Best Practices Unit, SOLABS

Brian Graeff's career in the Pharmaceutical industry spans over 39 years. He has held various management positions in Quality Assurance, Quality Control and Production. Brian brings a wealth of experience in pharmaceutical manufacturing, quality management, and CGMP interpretation and implementation to SOLABS. He believes that "focusing on the fundamentals" is the key to product quality, compliance and maintaining a company's license to operate.



Anne-Marie Pinet, Product Analyst, SOLABS

Anne-Marie Pinet is passionate about being among the first points of contact for many SOLABS QM clients and implementations. As a Business Analyst with over 25 years of experience in computer science, mainly acquired in the Life Science Industry, Anne-Marie is known for her strong analytical skills and for her ability to think outside of the box. Some of her key drivers are team spirit and customer/end-user satisfaction.

OOS | APP-P0038 Flowchart

? = Decision

BRIAN GRAEFF SAYS

"Virtual Companies are usually involved in Phase II of an OOS investigation, the Manufacturing Investigation."

In this case, Phase I is the Laboratory Investigation, and everything that precedes the Manufacturing Investigation."

