

DEVIATION | APP-P0027

Overview

DEVIATION | APP-P0027

Overview

Developed for companies in the following industries:



BIOTECH



MED DEVICE



PHARMA



R&D



VIRTUAL

ABOUT THIS QM APP

"Last year, when we went to a client site, we brought the best Deviation APP we had at the time--APP-P0027. We called it a Deviation Process, but the client preferred to call it a Deviation/Non-Conformance Process.

From our standpoint, it doesn't really matter what you call it; we all know that it's part of a larger category, which we like to refer to as Quality Events--and what really matters is its effectiveness.

The most critical step in this process is likely the Risk Assessments, which come with Extension Requests; the former allows a thorough scoping and evaluation of the situation's gravity, while the latter allows a lot of flexibility, while remaining fully compliant."

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

HIGHLIGHTS

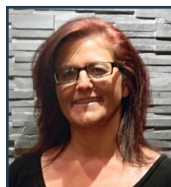
- After Step 2, an **Impact Assessment** is made in order to determine how to escalate and proceed
- As an outcome of the **Impact Assessment** results, the **Investigation** is then either simply executed, or planned then executed
- A dependent **CAPA process** may be triggered as a result of the investigation if it is determined to be necessary
- Both **Extension Requests** (approved by QA and permitting more time when required) and **Additional Tasks** (tasks upon which the completion of the process depends) branch off from Step 5, and are used when and as required
- Step 5C processes various **Additional Approvals** in parallel, where the approvals are dependent on one another for completion and advancement to the next step
- At Step 6, **Final QA Assessment** is either approved by QA, or, in the case where any major Impact Assessment changes are made (minor to major, major to critical, i.e.), the only available action is to return to initiator for further assessment

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.

DEVIATION | APP-P0027 Flowchart

ANNE-MARIE PINET SAYS

“One of the reasons Brian [Graeff, Head of SOLABS’ Quality & Best Practices Unit] and I work so well together is that each of us brings our talents and experience to the table. He’s held executive level compliance and regulatory positions in private companies, and reads up and stays current with the news, and I know what SOLABS QM is capable of, what Life Sciences workplaces are like at ground-level, and how to map ‘in real life’ workflows onto our software. We have a highly complementary working relationship, to the point where clients are sometimes able to shave time or steps off established workflows.

This NCR/Deviation establishes that we spend a lot of time listening to and learning from our clients, and that we’ve optimized their processes—and, in this case, that we’ve built some next-level safeguards and flexibility into the process itself.

We’ve been explicit with our intent when laying out steps, and each time we’re careful—as with the Impact Assessment in Step 1—it’s for a rock-solid reason: in this case, to scope accurately, to determine the potential impacts, and to have a really well-defined idea of the situation from the inception of the process.”

