



# **OQ for Chemical Passivation of Implants - CASE EXAMPLE (Technical Series on Process Validation Principles and Practices)**

*Robert Mitu*

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This document focuses on operation qualification (OQ) for the chemical passivation process for medical device implants.

Although the process parameters used by most manufacturers are aligned with those established by ASTM standards, it is urged that manufacturers verify the limits for their specific products. The ASTM standards provide several options that a manufacturer can use to chemically passivate stainless steel products; however, not all the options will be appropriate for every kind of stainless steel material used to manufacture implants. Thus it is necessary to validate the process in the actual manufacturing environment irrespective of the source of process parameter limits.

The example in this document includes both the OQ protocol and its respective report and contains the following sections: risk assessment, statistical rationale, sample preparation and testing, acceptance criteria, revalidation requirement, among other sections.

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