

**RISK-BASED CALIBRATION INTERVAL ADJUSTMENT OF SENSORS IN
PHARMACEUTICAL MANUFACTURING MACHINES**

By

Josephine Anabel Jasmin
12204010

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SWISS GERMAN UNIVERSITY
The Prominence Tower
Jalan Jalur Sutera Barat No. 15, Alam Sutera
Tangerang, Banten 15143 - Indonesia

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STATEMENT BY THE AUTHOR

I hereby declare that this submission is my own work and to the best of my knowledge, it contains no material previously published or written by another person, nor material which to a substantial extent has been accepted for the award of any other degree or diploma at any educational institution, except where due acknowledgement is made in the thesis.

Josephine Anabel Jasmin

Student

Date

Approved by:

Dr.-Ing. Diah Indriani Widiputri

Thesis Advisor

Date

Prof. Dr.-Ing. Karsten Köhler

Thesis Co-Advisor

Date

Dr. Hery Sutanto M.Si. S.Si.

Dean

Date

Josephine Anabel Jasmin

ABSTRACT

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By

Josephine Anabel Jasmin
Dr.-Ing. Diah Indriani Widiputri, Advisor
Prof. Dr.-Ing. Karsten Köhler, Co-Advisor

SWISS GERMAN UNIVERSITY

Calibration intervals in pharmaceutical manufacturing are commonly fixed rather than justified by individual sensor performance. This is contrary to ILAC G24 (2022) and NIST GMP 11 (2019), and misaligned with the risk-based principles of ICH Q9(R1) (2023). This study develops a structured decision-making tool for adjusting sensor calibration intervals, developed for application at groninger's pharmaceutical sterilising and filling machines. The tool integrates control chart analysis of historical calibration data, the Analytic Hierarchy Process (AHP) for prioritising drift-influencing factors, and an adapted Failure Modes and Effects Analysis (FMEA) for risk scoring. It was applied to a PT100 RTD, a differential pressure sensor, and a load cell to demonstrate its use. The PT100 and differential pressure sensors were found statistically stable across calibration histories of eighteen and seventeen years respectively; AHP identified component ageing as the dominant long-term drift driver, while the adapted FMEA identified mechanical damage as the highest short-term risk. The resulting framework offers groninger a regulatory-compliant, sensor-specific alternative to standardised calibration cycles.

Keywords: Sensor, Calibration Interval Adjustment, Sensor Drift, Analytical Hierarchy Process, Failure Modes and Effects Analysis, Pharmaceutical Manufacturing



DEDICATION

To our efforts in measuring the limitless...



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