This certifies that

Carina Buur Egsgaard

has successfully completed

GAMP 5 Introduction

Good Automated Manufacturing Practice (GAMP) provides the opportunity to follow a logical and systematic approach to categorization, documentation, and risk assessment of automated systems.

During the course, the participant has acquired knowledge of:

- Relevant GMP rules and guidelines for the development and verification of automation systems.
- Where inspiration and guidance can be found for creating relevant documents, and which phases to go through in planning, development, and testing of the systems.
- The issues at different life cycle stages and at different levels of complexity.
- How risk is managed in relation to patient safety, product quality and data integrity.
- How specification and verification material can be scaled according to risk.
- How you, as a pharmaceutical manufacturer, can involve the subcontractor in the overall validation activities and thus avoid unnecessary duplication of work.
- How you as a subcontractor live up to pharmaceutical manufacturers' expectations of good practice with subcontractors.
- How software categorization can reduce the required documentation and validation activities.