



EUROPEAN COMPLIANCE,  
ACADEMY

# Certificate

**Mr. Honoriu Pavel Dumitrescu**

has completed a four day ECA GMP Education Course from  
**9 - 12 December 2019** in Copenhagen, Denmark covering the following subject

## ***Pharmaceutical Engineering***

### **Contents of the Course:**

An Overview - How Engineering impacts on GMP and the Regulatory Area  
Overview - The important Documents in the Pharmaceutical Industry

SOP- Requirements and Basic Rules of Writing

FDA-Compliant Design of Vessels, Piping, Valves and Gaskets

Hygienic Design Principles and Practical Examples

Qualification and Validation, Risk Analysis, URS/FDS, DQ, FAT/SAT

IQ,OQ,PQ - Requalification, Process Optimization, Process Validation, Cleaning Validation

GMP-compliant Management, calibration in Pharmaceutical Production Processes

Change Control/Deviations, Audit

Workshops: Documentation - SOP, GMP-conform Design, Qualification

Heidelberg, 12 December 2019

Signature of Course Leader

In co-operation with

**CONCEPT  
HEIDELBERG**