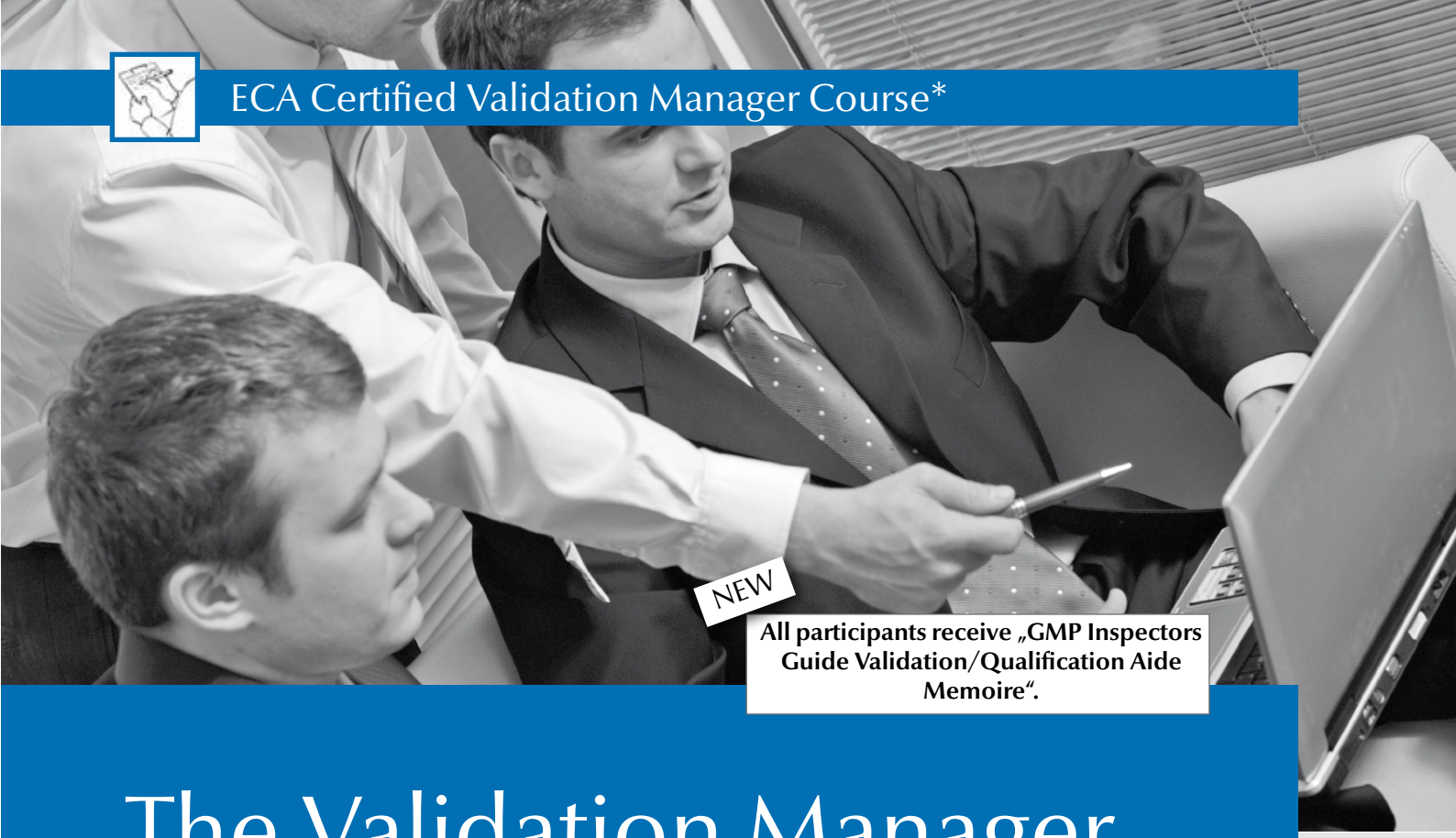
ECA Certified Validation Manager Course*



NEW

**All participants receive „GMP Inspectors Guide Validation/Qualification Aide Memoire".**

# The Validation Manager

Overview of the cGMP requirements on the whole range of validation/qualification

16-18 November 2011, Budapest, Hungary

SPEAKERS:

Lynn Bryan
*Ballygan Consulting, UK*

Dr Christopher Burgess
*Burgess Analytical Consultancy, UK*

Dr Norbert Skuballa
*Biologische Arzneimittel Heel, Germany*

Dr Wolfgang Schumacher
*Hoffmann-La Roche, Switzerland*

PROGRAMME:

- Regulatory Requirements
- Risk Assessment
- Validation Master Plan
- Qualification
- Validation
- Computer Validation
- Cleaning Validation
- Qualification/Validation in API Manufacturing
- Change Control
- Case Study Qualification
- Case Study Validation

With practical examples on CD ROM

ECA
European Compliance Academy

*This education course is recognised for the ECA GMP Certification Programme „Certified Validation Manager". Please find details at www.gmp-certification.eu

# The Validation Manager

16-18 November 2011, Budapest, Hungary

## Learning Objectives

For years, the topic validation/qualification has been among the top deviations in FDA's warning letter statistics. This is true both of pharmaceutical manufacturers and of the API industry. Other frequent citations refer to the related topics cleaning validation and change control. What is also checked during inspections – and mentioned in warning letters – is computer validation. In order to give you an overview of the cGMP requirements on the whole range of validation / qualification, we have designed the practice-oriented 3-day GMP Education Course „Validation Manager" for you. In many pharmaceutical and API enterprises, the Validation Manager has become an established function.

One focus will be on the **new FDA Guidance on Process Validation**. What are differences, what are similarities to European validation guidelines?

Parallel workshops on risk analysis and detailed case studies on qualification and validation help to consolidate the theory and demonstrate the practical implementation.

## Target Group

The addressees of the event are qualified staff charged with or responsible for validation activities such as commissioners for validation, heads of quality assurance, department heads, etc. It also addresses members of validation teams (e.g. engineers, chemists, pharmacists, microbiologists) as well as representatives of the plant engineering industry and consultants.
**Note: The number of participants is limited to 40 persons.**

## Social Event

The European Compliance Academy cordially invites the conference participants to join them and the speakers for a social event on Wednesday evening. During an informal dinner you will have the opportunity to meet and discuss the hot topics of the day with your colleagues.

NEW

**All participants receive the "GMP Inspectors Guide Validation/Qualification Aide Memoire"**

Validation/Qualification Aide Memoire (GMP Inspectors Guide) developed by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) – English translation. This 52 page document covers the whole spectrum of validation and qualification (including Cleaning Validation, Validation of Analytical Procedures and Change Control). The Aide Memoire is really helpful as a tool to prepare for an Authority's GMP Inspection.

## Programme

### Overview

#### Regulatory Requirements on Qualification / Validation Aspects

- EU GMP guideline and annexes
- PIC/S guidelines
- Systematics of plant qualification and process validation
- New approaches to validation
- The new FDA Draft Guidance on Process Validation

### Industrial View

#### Risk Assessment

- Why is risk assessment necessary?
- ICH Q9
- Risk assessment techniques
- Case study

#### Validation Master Plan

- Target
- Format
- Content
- Differences between PIC/S and Annex 15
- Validation Master Plan and Lost Guide

#### Qualification

- Why do we do this - history
- DQ, IQ, OQ, PQ – how the stages of validation fit together
- How to handle qualification logistics?
- Re-qualification
- Qualification of equipment in use

#### Case Study Qualification

The case study describes how a purified water system can be qualified according cGMP.

#### Case Study Validation

The case study describes a process validation study of a tabletting process.

#### Validation

- Prospective vs concurrent vs retrospective validation
- The new FDA Draft Guidance on Process Validation
- Are 3 runs still valid?
- Revalidation
- Pitfalls

#### Computer Validation

- Organisation of computer validation
- Classification (GAMP® 5)
- Risk analysis
- Change control
- Legacy systems

### Cleaning Validation
- Validation protocol
- Risk assessment
- Sampling
- Which limits are acceptable?
- Case study

### Qualification/Validation in the Field of API Manufacturing
- Guidelines focused on qualification/validation aspects for API production
- GMP requirements for qualification/validation in the field of API manufacturing
  - Differences to drug manufacturing
  - Retrospective qualification
  - Revalidation
  - Pitfalls

### Change Control
- Technical change control
- Regulatory change control
- Change control documentation

**Workshops**
We offer three parallel workshops. You can take part in one of the workshops.

**Workshop 1**
**Organization of Validation**
An interactive workshop to find out and discuss how validation activities can be implemented in an existing QM-Sysem and how to write a Validation Master Plan

**Workshop 2**
**Risk Assessment Product Introduction**
In the workshop you look at risk assessment associated with new product introduction of a sterile product. You will put together a plan of the critical items which will need to be addressed, initially at high level (product, process, people, premises, paperwork). From this you will then assess the high risk areas and assign actions associated with these areas.

**Workshop 3**
**Risk Assessment Process Validation**
An interactive workshop to find out and discuss GMP-relevant aspects of the validation of tabletting.

## Speakers

**Lynn Bryan** *BSc. (University of Liverpool) P.G.C.E (University of Reading), UK*
Lynn has had Qualified Person status within the industry for 5 years and is currently working as a QP for a radiopharmaceutical manufacturer and also has her own QA/Validation consultancy business. Previously Lynn headed several managing positions in the pharmaceutical industry (e.g. validation manager at Ipsen Biopharm, production support manager at a contract aerosol manufacturing company, director of an independent validation company). Lynn has been presenting on training courses on validation, training approach, GMP and water/steam systems for over 10 years.

**Dr Christopher Burgess**
*Burgess Analytical Consultancy, UK*
Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

**Dr Norbert Skuballa**
*Biologische Arzneimittel Heel, Germany*
Norbert Skuballa is head of the Pharmaceutical Compliance Management function at Heel and responsible for development and coordination of all compliance related GxP and regulatory affairs processes. He has been working in the pharmaceutical industry since 1991, mainly for Schering (now Bayer Pharmaceuticals) in Research, Production and Quality Management.

**Dr Wolfgang Schumacher**
*Hoffmann-La Roche, Switzerland*
Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he headed different positions. In 2001 he joined F. Hoffmann-La Roche, Basle, where he is in the Quality Unit of information technology, the quality assurance of global applications and the qualification of the IT infrastructure. He is a member of the ECA Advisory Board.

### Become a Certified Validation Manager!
The GMP Certification Programme has been expanded with a new certification module – the module **Certified Validation Manager**. The GMP Certification Programme (ECA) is the leading European qualification system for professionals in the GMP/FDA-regulated environment. If you are interested in this programme, you will have to attend three programme approved seminars. As in the other certification modules you can assemble the seminars for approval according to your interest and focus. The only mandatory seminar is the 3-day intensive seminar „The Validation Manager." **You will find more information about the programme at www.gmp-certification.org**

## Easy Registration

**Reservation Form:**
**CONCEPT HEIDELBERG**
**P.O. Box 10 17 64**
**69007 Heidelberg**
**Germany**

**Reservation Form:**
**+ 49 6221 84 44 34**

**e-mail:**
**info@concept-heidelberg.de**

**Internet:**
**www.gmp-compliance.org**

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

**The Validation Manager,** 16-18 November 2011, Budapest, Hungary

Please choose one workshop:

- ☐ Workshop 1: Organisation of Validation
- ☐ Workshop 2: Risk Assessment Product Introduction
- ☐ Workshop 3: Risk Assessment Process Validation (Tabletting)

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

**Please indicate your company's VAT ID Number** | **P.O. Number if applicable**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

**General terms and conditions**
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
**Terms of payment**: Payable without deductions within 10 days after receipt of invoice.
**Important**: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

### Date

Wednesday, 16 November 2011, 09.30 h - 18.00 h
(Registration and coffee 09.00-09.30 h)
Thursday, 17 November 2011, 8.30 h - 18.15 h
Friday, 18 November 2011, 8.30 h - 13.00 h

### Venue

Hilton Budapest WestEnd
Váci út 1-3
1062 Budapest
Hungary
Phone +36 1 288 5500
Fax +36 1 288 5588

### Fees

ECA Members: € 1,790,- per delegate + VAT.
APIC Members € 1,890.- per delegate plus VAT (does not include ECA membership).
Non-ECA Members: € 1,990,- per delegate + VAT.
EU GMP Inspectorates: € 995,- per delegate + VAT.
Including: Conference documentation, lunch and dinner on the first day, lunch on the second day, all refreshments, social event

### Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel (room rate € 119,- per night incl. breakfast, excl. VAT and city tax). Please make your reservation via the Personalised Online Group Page **http://www.hilton.com/en/hi/groups/personalized/B/BUDWEHI-GCONE-20111110/index.jhtml** where you also can modify/cancel your reservation. Reservation should be made directly with the hotel not later than 5 October 2011. Early reservation is recommended.

### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at **www.gmp-compliance.org.**

### Conference Language

The official conference language will be English.

### Organisation

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