

BIOTECH QUALITY MANAGER / REGULATORY AFFAIRS MANAGER

– JOB INSIGHTS AND TRAINING –

1-day interactive workshop for international graduate schools

Trainer: Dr. rer. nat. Christian Grote-Westrick

Keywords:

Total Quality Management, Biotech Management, Regulatory Affairs for Drugs and Diagnostics, Corrective and Preventive Actions, Audits in Companies by Authorities, EMEA, FDA, GMP

Abstract:

Quality Management becomes obligatory for companies producing medical products such as drugs and diagnostics. Especially international business and approval requires certified quality management systems thus new quality managers have quite attractive job prospects these days.

For reproducible processing in biotech manufacturing and also total traceability at all stages of production quality managers in biotech industry face several important tasks and challenges. This workshop illustrates the job of quality managers in biotech companies dealing with general regulating documents (ISO 9001), medical products (ISO 13485), analytical and calibrating services (ISO 17025) and US market approvals (510(k) procedure). Within this workshop participants will construct an own quality management system for their own fictional company with different product focus.

Workshop directory:

1. Introduction into quality management
2. Setup of quality management handbooks
3. How to certify quality managements
4. Case studies: quality managements of biotech companies
5. Approval of medical products based on QM systems (European Union, United States of America, Asian Markets)

6. Interaction (setup of quality management for own company)

3 groups:

Company 1: QM system compliant to ISO 9001

Company 2: QM system compliant to ISO 13485

Company 3: QM system compliant to ISO 17025

7. Job Preview: Quality Manager (Tasks and Goals)

Introduction:

Since quality of products is expected from customers in any kind of business manufacturers of medical products have realized that without a QM (quality management) system it will be hard to convince new customers or distribution partners in different countries of reliable product quality at any time. Thus the setup and maintenance of a quality management system (in general compliant to DIN EN ISO 9001) becomes obligatory. If a medical product has been categorized by the European Union as risky or even very risky in terms of patient endangering, it may be also necessary to receive a certification of the own quality management system on the part of an authorized facility such as TÜV, DEKRA, MEDCERT or MDC. In this case a characteristic symbol of quality such as the CE label may only be carried upon product labels in case of successful certification.

With a CE label export to EU member states is enabled without the need of approval in these countries. But in non-EU countries such as emerging states such as China, India or United Arab Emirates individual approval becomes necessary which includes a lot of challenges and pitfalls. The premise for a certified quality management is proper implementation of the technical documentation of a medical product into the existing QM system. Setup of technical documentation and its components such as validation, risk management or stability data are trained at the workshop “project management in biotech industries”. Tempting goal of medical product manufacturer is export to United States of America. Here special approval phases must be faced in terms of diagnostics and therapeutics. Here the easiest way is the 510(k) procedure that is made up by a pre-market approval (PMA) checking for a comparable medical product on the US market to show similarity to facilitate market introduction. The job of quality managers / regulatory affairs managers in biotech companies has developed to one of the most important position because they coordinate the setup and maintenance of a quality management system, they control documents and their distribution within the company, they report directly to management boards, and they are contact persons for audits on the part of authorities – summarized: quality managers are responsible for reliable quality of the company’s products.

Aims of this workshop:

Participants of the workshop “biotech quality manager – job insights and training” will receive detailed information of 3 different quality management systems that can be found in biotech companies. ISO 9001 can be found in every part of business (industry or university) and is applied in more than 140 countries. It represents a general quality management system for proper documentation and reliable product characteristics. ISO 13485 displays a specialization of quality management for medical products defining product particulars and hazards of a diagnostic or therapeutic product. Offering analytical services in terms of pharmaceutical, cosmetic or food analysis

a suitable quality management is compliant to DIN ISO/IEC 17025 for testing and calibration laboratories. These three management models will be introduced and deepened by individual case studies.

Quality managers / regulatory affairs managers also deal with approvals of medical products in different countries. Here specific documentation packages and distinct requirements have to be prepared and communication to authorities must be cultivated to reduce time to market as much as possible. Range of responsibilities is manifold and display key liability for all business areas of a biotech company. This workshop will point out major challenges for approving a medical product for different countries (EU, non-EU) in the form of checklists. Case studies will show successful introduction of medical products to different markets (EU, US, Asian Market).

Every participant will receive a certificate of completion displaying treated topics and trained quality management systems.

The importance of quality management systems especially in biotech industry gives importance to this workshop. In combination with

the workshop “project management in biotech industries” this seminar offers comprehensive preparation of young PhD professionals for a quality management job in industry.

Contact person:

Dr. Christian Grote-Westrick
Johanneskamp 12
46282 Dorsten

Phone: 02362-789-7520
Cell Phone: 0177-8772765

Email: info@grote-westrick.com



Grote-Westrick.com ○ Johanneskamp 12 ○ D-46282 Dorsten ○ Telefon: 0049 (0)2362 789 1128 ○ Telefax: 0049 (0)2362 789 1129 ○ Mobil: 0049 (0)177 877 276 5
Email: info@grote-westrick.com ○ www.grote-westrick.com ○ Freiberufliche Leitung: Dr. rer. nat. Christian Grote-Westrick ○ Steuernummer.: 359/5137/5833

Grote-Westrick.com

Since 2008 the organisation Grote-Westrick.com is pursuing the goal of mediating essential and advanced aspects to prospective industry starters in fields of biotech and biopharma. These aspects comprise data from industrial work routine that shall deliver advantages for job prospects and advices for a successful start in biotech companies. Because academic workshops rarely touch industry-relevant topics, in 2008 these workshops were developed for scientists, medical students and engineers who aspire entry into biotech industry.

These workshops deal with essential questions of young PhDs:

- *what is expected from fresh PhDs in industry?*
- *how does daily routine look like in leading industrial positions?*
- *which keywords are obligatory for successfull application or interview?*

This workshop enjoys national popularity; in particular former participants described this workshop as very helpful being a reference for application and interviews before entering biotech industry.

Administration:

Dr. rer. nat. Christian Grote-Westrick



2000-2004 Biochemistry studies at Ruhr-Universität Bochum
2004 Diploma thesis at Harvard Medical School, Boston, USA
2004-2007 PhD thesis at Ruhr-Universität Bochum / Yale University, USA,
2007 Research Associate at Solvay Pharmaceuticals GmbH, Hannover
2007-2008 Project manager at imusyn GmbH & Co. KG, Hannover
2008-2010 Director recombinant protein production at imusyn GmbH & Co. KG
2010-2011 Head of production at Dr. Fooke Laboratorien GmbH
2011-2013 Manager Development and Production at BDL Diagnostics GmbH, Münster
since 2013 Quality Manager at B.Braun AG
since 2008 Freelancing Trainer for Graduate Schools workshops