# Curriculum Vitae

## Personal information

Anders Bäcksholm

## Work experience

*2018-May – April 2023. Corporate QA Manager reviews and project, Octapharma AB, Stockholm, Sweden.*

Job assignments:

- QA lead for various corporate projects e.g. Russian fractionation and filling plant in Skopin (green field project, concept design, basic design, quality project plan), new manufacturing execution system, new Learning Management System, new Drug Safety database, new LIMS-system.
- Member of reference group for the new Panzyga production line in Springe, Germany and Lingolsheim, France and for the new base fractionation production line in Stockholm, Sweden.
- Review and QA-approval of qualification and validations of corporate equipment and IT-systems including process URS, equipment URS, impact assessment, risk classification, validation plans, design qualification, FAT/SAT/IQ/OQ/PQ.
- Review and approval of corporate SOPs and work instructions for my work area and development of corporate quality processes.
- Performing quality audits of Octapharma manufacturing sites (intersite audits), external audits of IT-suppliers, service providers (e.g. construction and validation services) and contract manufacturing of Octapharma products (I'm certified QA-auditor).
- Leading and coordination of Octapharma CC-managers corporate forum
- QA responsible for industrial customers and QA supply related topics such as QA-agreements, third party audits and customer questionnaires.
- Development and supporting the implementation of a quality system and a new local QA-organization at Octapharma Russia.

*2016-Nov – 2018-April. Compliance Manager, Valneva AB, Stockholm, Sweden.*

Job assignments:

- Performing internal GMP inspections of Valneva departments and systems against various GMP guide lines e.g. EU GMP Part I and II and its annexes, GDP, PICs data integrity, GAMP5 and ISO clean room standards etc.
- Co-auditor of external supplier audits
- Responsible for quality agreements with suppliers
- Organizing the management of external inspections on site at Valneva and back office lead (e.g. regulatory and customer inspections).
- Member of Quality Review Board
- Provide GMP support to the organization.
- Provide training in GMP and GDP

*2013-May – 2016- Nov, QA Manager, Octapharma AB, Stockholm, Sweden.*

Job assignments:

- QA-project rep for the set-up, implementation, room layout and qualification activities of a new LVP (Large volume parental) filling line for multiple products. In scope where the vial washing machine, sterile heating tunnel, isolator, the filling machine, stoppering, capping and coding machine and also the HVAC system, monitoring and other supporting processes.
- Participating in FAT (factory acceptance testing) for the LVP-project
- QA responsible for the aseptic production such as sterile filtration, filling, freeze drying and environmental monitoring of clean rooms. Responsibility includes approval of qualifications and validations (including new strengths and products), re-qualifications of equipment and HVAC-systems, change requests, performing approval of SOPs, review and approval of media fills and annual trending reports for environmental monitoring.

- Writing SOPs

- LEAN development of ways of working (e.g. developing the complaint management procedure to reduce lead time and updating the SOP accordingly).

- LEAN 6 sigma green belt with mini tab.

- Hosting of on site regulatory inspections such as the US FDA (both PAI and general GMP inspections), Sweden (Läkemedelsverket), Brazil, Iran, Mexico, Turkey, Belarus and several industrial customer inspections. Activities of being the "host" includes; accompany the inspector in war room and guided tours on site. Coordination of questions, answers and presenters making sure that the inspectors getting their questions answered.

- Supporting local QA functions with QA agreement management and "general GMP".

- Supporting internal GMP-inspections occasionally as co-auditor and SME.

- Responsible for compilation of Product Quality review and Annual Product Review reports according EU, US and Canadian guidelines for all the products manufactured at Octapharma Stockholm (ended Feb 2016).

- QA responsible for the Octaplas production (ended Feb 2016).

- Responsible for customer complaint management, coordination of and reviewing investigations and supporting QP (ended April 2015).

*2009-July – 2013-May, QA Supply Manager, GES QA, Global Direct Materials Supply, AstraZeneca AB, Södertälje, Sweden.*

Job assignments:

- QA Supply Management of external suppliers of direct materials (e.g. excipients)

- Negotiating, agreeing and signing of Global QA agreements with external suppliers

- Managing material complaints, reviewing and approval of suppliers' delivered investigations.

- Developed a global guide line for "internal AstraZeneca" material complaints.

- Change management (global changes and QA lead in global change souring projects)

- AstraZeneca representative in the European IPEC work group for the update of the IPEC change guide line.

- Deviation and issue management, supporting local QAs at the different AZ sites.

- Quality review meetings through support from continual monitoring of performance "KPIs", agreed actions and continuous improvements with Global Suppliers/Vendors.

- QA risk assessments of suppliers, compliance and QA KPI reporting including setting risk mitigation actions.

- Supplier qualifications and selection.

- QA responsible for the TAIL project (Implementing a new global distributor for AstraZeneca, (approx 400 materials and 180 suppliers in scope))

- Global QA representative in process chemicals subcategory team

- Review and commenting on audit observations and responses from Supplier audits.

*2008-Sep – 2009 June*, QA Executive and Quality Assurance Officer (QAO), GES QA, API. AstraZeneca AB, Södertälje, Sweden.

Job assignments in **addition** to the QAO role job assignments:

- QA Supply Management of 7 API suppliers

- QA responsible for the outsourcing project of Formoterol to a vendor

- Coordinated the Japanese PMDA inspection of a supplier due to a product launch in Japan.

- QA representative in tactical team for local anesthetics

- Regulatory documentation management and business approval of such documents

- Negotiating QA agreements

- Managing complaints and reviewing suppliers investigations

- Change management

- Issue management

- Quality review meetings

- QA risk assessments of suppliers, compliance and QA KPI reporting

- Peer review of audits reports and observations

- Representative for GES at "grey zones" meetings with Sweden Operations QA.

- Mentor ship program for individual development and leadership capabilities

*2007-Feb – 2008 Sep*, Quality Assurance Officer, GES QA, AstraZeneca AB, Södertälje, Sweden.

Job assignments:

- Batch release of API substance (29), intermediates and raw material (8), reviewing laboratory results, approx 400 batches a year

- Writing CoA

- Approvals of master data (specifications and product articles)

- QA supply management of 9 GDMS suppliers

- GCM user (complaint management)

- Supporting supply management work

- Participating in the launch of the QA Category Lead positions, meaning transferring local QA supply management into a global organization for direct materials. Received a MAD award.

*2002-Nov – 2007-Feb* – Quality assurance officer, QHA – batch release, DSS, AstraZeneca AB, Södertälje, Sweden (senior role from 2005).

Job assignments:

- Batch release of API substance, intermediates and raw material, reviewing batch records and laboratory results, reviewing and approving deviations, change control and batch documentations

- GMP-approval of working procedures, validation protocols, qualifications, modifications, batch records masters and cleanings
- Writing standard operation procedures, annual product reviews and certificates.
- Teaching GMP to operators
- Quality advisor for production, QA-coordinator in qualifications and validation projects
- Project manager for a risk management project for deviation handling
- Managing customer complaints and customer contact
- Member of the management team for DSS outsourced products
- Hosting internal QA inspections
- Lean project to reduce lead time of QA API batch release, batch protocol reviews and development of new batch protocol templates for increase of "right first time".
- System administratior of CHG (IT-system for deviations and change control)

*2001-August until 2002-November* – Consult, research engineer, laboratory work at

Biotechnology Company Labteam Sweden, Amersham Biosciences, Proteomics

System integration, R&D, Uppsala, Sweden.

Job assignments:

- Verification of analytical system for protein analysis
- Planning of tests, manuals and instructions for the system

*2000-September until 2001-August* – Pharmacia, Process R&D, method development, Stockholm, Sweden.

Worked at analytical laboratory whose task was to develop analytical methods and validate.

Job assignments:

- Qualification and validation of analytical methods and instruments and transfer these to QC-departments within Pharmacia's manufacturing units
- Transfer of a gel filtration method to a manufacturing site in Belgium

## Education and training

*2022 GMP for Equipment, Utilities and Facilities, 3 days, ECA, Online training.*

*2020 Computer Validation; The GAMP 5 approach, 3 days, ECA, Vienna, Austria*

*2017 The GDP Compliance Manager, 3 days, ECA, Berlin, Germany.*

*2017 Practical auditing training, in-house program Valneva, Swede*

*2016 RABS and Isolator technology, 3 days, CVS, Amsterdam, NL.*

*2015 A-Z of Sterile Products Manufacture, 4 days, NSF, Manchester, UK.*

*2015 Håll dig uppdaterad i GMP. Webinar 1,5 hours. Key2Compliance.*

*2015 GMP-requirements for computerised system, ½ day, Key2Compliance, Stockholm.*

*2015 LEAN 6 Sigma green belt training, 2 weeks, Vienna Austria and Stockholm, Sweden (unfinished).*

*2014 Inspection Management - How to pass EU and FDA regulatory inspections, 3 days, ECA, Berlin, Germany*

*2014 Håll dig uppdaterad i GMP. Webinar 1,5 hours. Key2Compliance.*

*2013 How to write PQR/APRs. 1 day NSF, Manchester, UK.*

*2013 Production hygiene and aseptic techniques , 3 hours , Octapharma*

*2007 GMP Compliance Auditing, 2 days, Key2Compliance, Nice, France.*

*2006 Applied Project Management, 4 days, Wenell, Stockholm, Sweden.*

*2006 Contract manufacturing of medical drug products, 1 day, Läkemedelsakademin, Stockholm, Sweden*

*2005 Risk Management and Risk Assessment, 3 days, David Begg, Stockholm, Sweden.*

*2005 Analytical problem solving, 4 days, Phaedra, Södertälje, Sweden.*

*2004 Computer Systems Validation, 2 days, David Begg, Stockholm, Sweden.*

*2004 Grundkurs i kvalitetssäkring vid läkemedelstillverkning, 3 days, Läkemedelsakademin, Stockholm, Sweden*

*2003 Batch record review and product release 1 day, David Begg, Stockholm, Sweden*

*2003 Effective Decision Making and Problem Solving*

*2003 Quality assurance for batch release officer, 4 days, AstraZeneca, Södertälje, Sweden.*

*2003 Validation of medical manufacturing, 2 days, Läkemedelsakademin, Stockholm, Sweden*

Education

*2016* Galenic pharmacy 7,5 hp. Uppsala University

*2016* Medical Chemistry, 7,5 hp. Umeå University

*2015* Microbiology 10 hp. Uppsala University

*2013* Commercial Law, 7,5 hp. Högskolan Kristanstad.

*2006-2008* Business & Administration, course A and B, 60 hp, Uppsala University

*1995 - 2000* Master of Science, Biochemistry, 240 hp, Uppsala University.

*1992 - 1995* Senior Secondary School, Borlänge, Sweden. Course Program: Natural Sciences.

## Additional information

Publications

Projects

Memberships

Other Relevant Information