EPSILON PLUS

Carsten Lund
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Summary

Carsten Lund:

I have master degree in mechanical engineering from the Polytechnic University in Denmark with a master thesis about injection moulding thin walled parts.

My first job was process engineering, trouble shooting, optimization ect. in a medical device company. This lead me to more involvement in process validation including the quality aspect of statistical analysis and documentation. Later I was a senior project manager where one major project was completion and implementation of the design & development procedure; from the very first design input through to the completion of design transfer.

My next job was QC manager which grew beyond the QC department to include metrology, test moulding and pilot production. The company entered the medical device business and then my role was process validation; procedures, analysis, documentation and training.

EpsilonPlus:

In 2009 I decided to become self employed and started EpsilonPlus. Working as a consultant with expertise in moulding, other plastic processes, quality management, applied statistics etc. I have enjoyed clients as small as 19 employees and as large as 90.000. I have worked with Danish companies but also French, German, Swiss and Irish companies (I lived in Ireland for about a year).
I have worked with technical companies, medical device manufacturers and food industry and my roles have covered QA management, training, Statistic analysis and documentation and much more.

EpsilonPlus is associate partner in RISMA, a software company specialized in risk management, project management and gap analysis tools (GDPR, White washing, Anti Corruption, ISO 9001, ISO 14001 and ISO45001).

EpsilonPlus is also a partner in Proces 360 which is an engineering, project management and quality management consultancy team.

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PROFILE

Experienced and process-oriented consultant for life-science industries.
Specific expertise in injection moulding, validation and Six Sigma applied statistics.

Injection moulding:

- Scientific Moulding and Optimization
- Process validation
- Specifications & Documentation
- Training
- Project Management

GMP, Qualification & Validation:

- Process validation
- Applied statistics
- Protocols, analysis and reports
- IQ/OQ/PQ documentation and execution
- URS /technical specifications
- FAT/SAT
- Training
- Project Management

Engineering:

- M.S.;Mechanical engineering
- Lean/Six Sigma (black belt) Process optimization
- Risk analysis (e.g. FMEA)
- Root Cause Analysis
- Design of Experiment
- Measurement system analysis (Gauge R&R)
- SPC
- Supplier and sub-contractor interaction
- Design Review
- Project Management (DMAIC)

Quality Management:

- Process oriented quality management & auditing
- Process mapping
- Risk analysis (ISO 14.971, HACCP, FMEA and other)
- Quality statistics
- Documentation (SOP's, semiautomatic records etc.)
- ISO 9001:2015
- ISO 13485/21 CFR820
- ISO 22.000
- Project Management

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EXPERTISES

+ Injection moulding

- Master thesis about thin wall moulding from Denmarks Polytechnical University (DTU)
- Scientific moulding trained by G&A Moulding and has worked hands on with process optimizations since 1997
- Process validation protocols, executions, analysis and reports completed in several projects. Process window OQ defined through DoE.
- Review and trouble shoot existing processes.
- Training injection moulding operators and engineers in the use of scientific moulding and how to document the procedure through customized workbooks.

+ GMP, Qualification & Validation

- Systematic approach to process analysis for validation planning using Lean/Six Sigma tools. Including Six Sigma tools in validation ensures the required statistical evidence and will often reduce the time to completion e.g. by reducing sample sizes or using well planned DoE's.
- Applying risk analysis and process oriented methods when planning and preparing.
- Using well documented statistical methods for sampling and for data analysis
- Bringing GMP "down to earth" to show how this is a helpful tool in the daily work.
- Writing and implementing procedures for compliance with GMP/CFR820 and ISO 13.885

+ Engineering

- Trouble shooting, i.e. root cause analysis, which is supported by tests and experiments to reach the solution. Thereby using DoE, measurement system analysis etc. actively.
- Lean/Six Sigma black belt in 2008 but has been working with applied statistics and Six Sigma Methods like DoE since before 1999.
- Project management implementing new production lines for injection moulding and other automated processes of medical devices.
- Process oriented approach for risk analysis; project-, process- and product risk.

+ Quality Management

- Working in medical device manufacturing companies since 1997
- Implementing process oriented quality management systems for innovation (idea to manufacturing) under ISO 13.485 as well as defining qualification and validation procedures.
- Implementing ISO 9001:2015.
- QA activities like non conformance handling, product release, complaint handling, record keeping etc.
- Internal auditing as well as supplier auditing

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PROFESSIONNAL EXPERIENCE

Since September 2009: **Epsilonplus; Free lance consulting**

(Epsilon – Mid Zealand, Denmark)

- Injection moulding; optimization, validation, trouble shooting, training, equipment, documentation etc.
- Measurement system analysis (e.g. Gage R&R)
- Quality management system – ISO 13.485, ISO 22.000 and ISO 9001:2015
- Statistical analysis; Regressions, Experimental data (DoE), SPC etc.
- Project Management (production)
- Product/Process development; Risk analsyis, RCA
- Training in GMP, validation, measurement uncertainties, moulding,
- Implementing RISMA Execution (Project Activity control software)
- Semi-automatic registration systems in Excel
- Risk management medical devices (ISO 14971)

\+ Main projects

- Statistical analysis and reporting for qualifications and process validation
- Validation and transfer of multi cavity moulds for medical devices
- Establishing quality management system ISO9001:2015
- Commissioning, optimizing and validation in new manufacturing facility
- Quality Data reporting systems in Excel+VBA
- Reviews and support for revision of SOP's, corporate policies compliance, validation etc.
- Internal auditor in ISO 22.000, gap analysis for ISO 13.485 and ISO 9001
- Supplier audits under ISO 9001 and ISO 22000
- Quality manager, acting

June 2008/September 2009: **Lean/Six Sigma Manager**

(Sonion A/S – Roskilde, Denmark)

- Quality management system – ISO 13.485
- Management; Metrology, Test Moulding
- Training in process validation for moulding engineers and technicians
- Process validation documentation and analysis
- Six Sigma projects

\+ Main projects

- Define and implement process validation methods
- Process validation of 30 moulds
- Optimize quality inspection methods

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September 2005/June 2008: QC Manager
(Sonion A/S – Roskilde, Denmark)

- Management; Quality Control, Metrology, Test Moulding, Pilot Production
- Quality management system – ISO 9001
- Quality management system – preparing for ISO 13.485
- Establish registration and documentation
- Complaint handling Poland/Denmark
- Training in "understanding injection moulding" for quality personnel (PL/DK)
- Design Reviews and risk analysis for new parts and moulds

+ Main projects:
  - Reduce complaints by 40% while production increased 70%
  - Establish and implement quality management and improved registration
  - Improve communication across departments

October 2004/September 2005: Senior Project Manager
(Nunc A/S – Roskilde, Denmark)

- Project Management
- Process optimization and Scientific Moulding

+ Main projects:
  - Define and implement SOP for innovation; from handling new product ideas through equipment commissioning and process validation to manufacturing.
    The SOP was audited and certified 13.485 by Lloyd and then implemented on the USA sites as well
  - Project management for a new product and new production line including 3 moulds, injection moulding machine and automated laser printing system with unique item ID. Development and patenting work, equipment commissioning, software validation, process validation etc. (13.485 and CFR 820 regulated company)

May 2002/October 2004: Head of Process Technology
(Nunc A/S – Roskilde, Denmark)

- Process optimization and Scientific Moulding
- Trouble shooting and optimization of existing processes
- Process validation, (prepare, run, analyze and document) DoE's
- Strategic analysis of production / OEE tool etc.
- Part of the CAPA team
- Internal auditor

January 1997/May 2002: Process engineer
(Nunc A/S – Roskilde, Denmark)

- Process Set up for new moulds & machines
- Trouble shooting and optimization of existing processes
- Analyze and report quality data
- Process validation
- Project participation
- Internal auditor

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LANGUAGE & SOFTWARE

Danish: First language; Spoken and written within professional environment – Excellent writing skills

English: Usually spoken and written within professional environment – Excellent writing skills

Swedish: Speaks and understands enough to engage in a professional environment but not on the same level as in English – reads and write it

German: Speaks and understands enough to engage in a professional environment but not on the same level as in English – reads German, but writes very slowly

Software:

- Minitab
- MS Office – high level user in Excel
- Visual Basic for Excel – to create user friendly records etc.
- RISMA Execution; certified
- RISMA Business (Risk & Control); experienced
- Q-DAS; Destra
- Access
- Knowledge of ERP systems

Education

1996: Technical University Masters degree – Mechanical engineering – DTU Denmark

2001: Process oriented quality management and auditing by Dcide

2005: GAMP IV training by NNIT

2006: Personal Productivity by LMI

2007: Complete G&A Moulding training program

2008: Lean/Six Sigma Black Belt training by SBTI

2015: Certified RISMA Execution user

2015: ISO 9001:2015 by DTI

2019: ISO 14971