Monika Bak
M.Sc, PhD, RAC
Copenhagen University

Senior RA Expert MD and IVD

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medicologic®
Medical Device Development

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Competences

- Regulatory Affairs Certified (RAC) by RAPS in EU, US, ROW
- Certified PR 365: MD-QMS ISO 13485:2016 Lead Auditor CQI-IRCA
- Medical Devices and In Vitro Diagnostics products registrations: EU, US, China, Australia, Canada and ROW (mostly for high-risk products)
- Collaborations on all stages with NB, FDA, EMA
- Project management
- Vigilance
- Change Control
- Clinical documentation (example CER) and Clinical studies (with CROs)
- MDSAP

Key results

- 10+ years in the medical device industry. Worked in big corporations as well as extensive experience with MedTech startups.
- Leading project MDR for approximately 60+ products Class III.
- Leading high-class registrations in China including type testing.
- Successful submissions to FDA (several 510(k), DeNovo submission including eSTAR program) for both adults and pediatric patients' population.
- Always successful audit participant in the RA responsibility area.

Software/Standards

- ISO 13485 - Medical devices - Quality Management
- ISO 14971 - Medical devices - Risk management
- ISO 10993 - Biological evaluation of medical devices
- ISO 14155: Clinical Investigation – GCP
- IEC 62366-1 Usability
- EU Directives: Medical Device Directive MDD 93/42/EC, in vitro diagnostic directive IVDD 98/79/EC, AIMDD 90/385
- EU regulations: Medical device regulation 2017/745, In vitro diagnostic medical devices 2017/746
- FDA regulations: CFR 21 Part 820, Part 11, 803, 806
- ISO 14155: Clinical Investigation – GCP
- ISO 15223-1 Labelling of medical devices
- ISO 11135 - Sterilization of health-care products ETO
- ISO 11137-1 Sterilization using Gamma Radiation
- ISO 11607-1; -2 Packaging

Personal Characteristics

Monika is an energetic, highly driven, and passionate regulatory affairs expert with a keen interest in regulatory news and knowledge. She holds a degree in International Diplomacy (2010) and a PhD from Copenhagen University, showcasing her strong technical background. Her dedication to science has been recognized multiple times, including receiving the Student Nobel Prize honor from the President of the Republic of Poland and a nomination for the Young Investigator Award by Merck & Co. This unique combination of skills and achievements makes her an exceptional negotiator for companies in their communications with authorities.

In her free time, Monika enjoys spending time with her children, relaxing by the water, gardening, and organizing her home.

References

Medicologic A/S (present)
Senior RA expert

The Red Line Power and Fureso Medical ApS

Regulatory and Clinical Affairs Consultant
Class IIb MD (SaMD) technical file creation, meetings with Notified Bodies, writing and reviews of CER, FDA submission for implantable sterile MD, trainings, other

BioPorto Diagnostics

Director Regulatory Affairs prior Sr. Regulatory Affairs Manager

Lead MDR Class III for high number of products (products with animal tissue and medicinal substances), leading complex China registrations including product testing, Australia, Canada, 510(k)s, Delaware project, labeling, work with EMA other tasks

CooperSurgical

Senior Regulatory Affairs Specialist / Team Lead prior Specialist

Lead MDR Class III for high number of products (products with animal tissue and medicinal substances), leading complex China registrations including product testing, Australia, Canada, 510(k)s, Delaware project, labeling, work with EMA other tasks

Radiometer

Regulatory Affairs Specialist

Malaysia, China registrations, technical files creation, expansion of business, other tasks

Agilent Technologies

Regulatory Affairs Specialist

FDA warning letter for US Class III devices clearance, global registrations, changes for class III US products, vigilance including recall of class III, other tasks

World Health Organization (WHO) Headquater Copenhagen and **Food and Agriculture Organization of the United Nations (FAO)** Headquater Rome (3x internship during MSc)