



Aydin Mataji
MSc, pharmacy, Copenhagen University

Qualified Person (QP), API release

ID1029

Direct (+45) 61766162
Aydin.mataji@medicologic.com

medicologic[®]

Medical Device Development

Medicologic A/S
Arne Jacobsens Alle 17
Ørestad City
DK-2300 Copenhagen
Denmark

(+45) 48 24 51 13
contact@medicologic.dk
www.medicologic.dk

Competences

- NC/CAPA Process management
- Systematic problem solving (Coaching)
- Change request process management
- Validation Activities (URS, Equipment Qualification, and process Qualification)
- QP (Batch review and product release)
- QMS implementation (procedures/templates)
- GMP support in daily operation – shop floor
- Establish process for cleaning of classified areas and CNC

Software/Standards

Extensive knowledge in:

- ICH Guideline Q7 and Q10
- ISO13485:2016
- FDA 21CFR part 820
- IVDR

- Windows
- Microsoft Office 365
- QMS systems as:
- Agile and NovoGlow

References

Medicologic A/S (2022 – present)

Senior Consultant

Agilent Technologies Denmark ApS (2019)

Quality Assurance Specialist – Process Engineering

- CAPA review and coaching employees
- SPS facilitator
- QA review of validation activities
 - URS
 - Equipment Qualification
 - Process Qualification

Novo Nordisk A/S (2016)

GMP Support – Sourcing Warehousing

- Production support – shopfloor, daily compliance and quality
- Handling Nonconformities and CVP area expert
- Handling Change Request and CVP area expert
- Writing SOP
- Key responsible for cleaning of classified areas

Key results

- Implementation of DDKM (Den Danske Kvalitets model) IKAS at Nørrebro pharmacy
- Change request and NC expert for sourcing operation at Novo Nordisk.
- Key responsible for establishing a new process for cleaning of classified areas at the new Novo Nordisk warehouse
- Deputy manager with responsibility of 25 employees at Nørrebro pharmacy

Personal Characteristics

Aydin do not believe that we have problems, but challenges and every challenge has a solution. Sometimes with a pragmatic approach.

As person Aydin is loyal, values equal amount of respect from others and has the ability to stay positive in demanding periods with high work load.

He is good at communication and loves to share his experience with others. He works well in a multicultural environment where it is naturally for him to interact with people of different academic and cultural background.

Aydin has many years of experience in the production area in the pharmaceutical and medical device industry where cGMP and compliance is his main focus.

In his spare time Aydin enjoys fishing, play paddeltennis, coaching his son and his team mates in soccer.

Novo Nordisk A/S (2013)

QA Professional – DAPI, Human Insulin Purification

- QA review of nonconformities
- Batch review and product release (API)
- Instruct in cGMP and compliance
- Review and approve SOP
- QA support of daily operation

Nørrebro Pharmacy (2009)

Quality responsible

- Implementation of DDKM (Den Danske Kvalitetsmodel)
- Writing procedures

Deputy Manager

- Ensure the daily running of the pharmacy
- Wage administration responsible
- Timetable responsible
- Staff responsible
- Contact person for external stakeholders and healthcare persons