

## **Personal particulars:**

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## **Workplaces:**

**2023.08 – Consultant: Bench Testing, Implantica**

Responsibilities:

- Gap analysis of sterile barrier system
- Prepare the sterile barrier system bench testing plan: including extreme environmental conditioning, shipment simulation, packaging and functional tests
- Define the necessary unique distribution cycle (DC 2 according to ASTM D4169) proper for the planned logistics
- Define climate conditioning parameters depending on target market
- Create sterile packaging standard implementations and summary document
- Coordinate the bench testing process.
- Define the packaging test methods and create test descriptions

Projects:

- Testing of abdominal implant and its packaging system
- Testing of injection tool and its packaging system for the abdominal implant

**2022.02 – 2023.09 Consultant: MDR Remediation Specialist – Sterilisation and sterile packaging, Ypsomed AG.**

Responsibilities:

- Gap analysis for sterilisation and sterile packaging
- Coordinate the sterile barrier system developments
- Risk analysis of the sterilisation and sterile barrier system
- Define the sterilisation strategy of new products
- Prepare the sterilisation and sterile packaging process validation plan
- Prepare the sterilisation and sterile packaging Design Verification plan
- Create sterile packaging standard implementations and summary document
- Coordinate sterilisation and sterile packaging validation and verification
- Define the packaging test methods and create test descriptions

- Define the proper machines and tools for packaging tests
- Calculate the EO residual limits after sterilisation for new products
- Define microbiological limits (CFU limits) for new products
- Define endotoxin test frequency and limits
- Define physical contamination test frequency and limits

Projects:

- Development of infusion sets for diabetes care
- Development of ready-to-use patch injector
- Development of insulin pump system

**2020.10 – 2022.02                      Engineering Manager, Medicontur Ltd.**

Responsibilities:

- Coordinate the daily work of the engineering and maintenance team (10 employees)
- Ensure continuous production
- Improve manufacturing process, implement LEAN concepts
- Validation of new processes and equipment
- NPI – transfer newly developed products/machines into the production

**2019.10 – 2020.10                      Consultant and Business Analyst, Asseco Central Europe H.**

Responsibilities:

- Optimisation of production process with plant simulation software
- Real Time monitoring of material flow and production
- Simulation, implementation and monitoring of material handling with AGVs
- Clarify relevant customer requirements about the product
- Market research for possible customers

**2018.09 – 2019.10                      Deputy – Head of Development Center, BBraun Medical Kft.**

Responsibilities:

- R&D responsible for wound drainage and suction devices
- Substitute of the Head of Development Center in his absence
- R&D responsible for medical device packages, whole portfolio produced on site
- Coordinate projects, capacities and delegate tasks within the R&D group

Projects:

- Update or prepare documents to be compliant according to the new MDR regulation
- Development of new, crystal clear drain bottles with tube set to the US market
- Packaging optimisation – define new materials, harmonise current portfolio

- Coordination of packaging Process Validations and Design Verification based on ISO 11607-1/2
- Re-validation of the EO sterilisation cycle
- Prepare a new R&D lab – define layout, equipment, suppliers

**2016.09 - 2018. 09                      Development Project Manager, BBraun Medical Kft.**

Responsibilities:

- R&D responsible for wound drainage and suction devices
- R&D responsible for medical devices packages produced on site

Projects:

- Packaging optimisation – define new materials, harmonise current portfolio
- Coordination of packaging Process Validations and Design Verification based on ISO 11607-1/2
- Development of new, crystal clear drain bottles with tube set to the US market
- Supplier Audit – external lab
- Ensure the clean water supply for production
- Define frequency of testing and the sampling points of the clean water system
- Prepare URS for new production equipment
- Revise specifications and drawings of supplier.

**2015.09 - 2016. 09                      Development Engineer, BBraun Medical Kft.**

Responsibilities:

- R&D responsible for wound drainage and suction devices

Projects:

- Development of new, crystal clear drain bottles to the US market
- Implement new back check valve to drain bottles
- Revise specifications and drawings of supplier
- Verification of new components from alternative supplier

**2011.09. - 2013. 10.                      Project Manager, Varmegye Media Kft.,**

Projects:

- Support the tasks of web developers
- Ensure the right and fluent communication between the customers and web developers.

**2013.07.01 - 2013. 08. 16    Trainee at Orvostechnika Kft.,**

Projects:

- Develop a new, blood homogeniser machine for blood analysis

### **Education:**

|                      |  |
|----------------------|--|
| 2015 Summer Semester | Friedrich Alexander University, Erlangen,<br>Material Science, MSC - Erasmus+ Program        |
| 2014-2016            | Budapest University of Technology and Economics,<br>Faculty of Mechanical Engineering MSC    |
| 2010-2014            | Budapest University of Technology and Economics,<br>Faculty of Mechatronical Engineering BSC |

### **Language skills:**

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|------------------------------------|---------------|
| English Advanced language exam:    | C1            |
| German Intermediate language exam: | B2            |
| Hungarian:                         | Mother tongue |

### **Certificates and trainings:**

- ISO 13485; ISO 13485 – internal auditor
- Medical device packaging (ISO 11607-1 and -2; ASTM F1980, ASTM F1886, ASTM1929, ASTM F88, ASTM F2096, EN 868-5, EN 868-10)
- Transport simulation (ASTM D4169)
- Microbiology and sterile barrier system (ISO 15378, DIN-58953-6; DIN EN ISO 10993-1, ISO 10993-5, ISO 10993-7)
- Sterilisation (EN ISO 11737-1 and -2; EN 14644; EN 556-1 and -2; ISO 11135; EN ISO 14161)
- Member of the organisation: ASTM (American Society for Testing and Materials)
- Project management
- 4DX and 7 Habits (Franklin Covey)
- EU Directives (93/42/EEC, 98/79/EC and 90/385/EEC) (MDD)
- Regulation (EU) 2017/745 (MDR)
- Agile project management

### **Others:**

B category driving licence

Free time: travelling, self-improvement

Sports: running, football, wall climbing, tennis, squash, scuba diving