

Curriculum Vitae Maura Walsh BSc (Hons), PhD

Sterilisation, Microbiology and Compliance Consultancy

Experience

Boston Scientific Corporation

- Corporate Sterilisation Manager BSC, Ireland
- Sterilisation/Microbiology Manager Galway Facility
- Quality Systems Manager Galway Facility

National Standards Authority of Ireland

- Auditor with NSAI in Medical Device section
- Audited multinationals in US, Ireland & Europe

Vistakon (J&J) Ireland

- Start up facility
- Sterilisation/Microbiology Manager Vistakon, Limerick

National Medical Care

- Sterilisation/Microbiology Manager, Dublin facility

Genzyme Biochemicals

- R&D Engineer

Post Doctoral Experience

- Moynes Institute, Trinity College, Dublin

Significant Activities

- Corporate Sterilisation Manager at Boston Scientific for all Irish BSC sites using EO, Gamma and E-beam technologies.
- Significant experience in management of sterilisation activity; product and process validation including cardiovascular, vascular, procedure packs, drug device combinations and large implantable devices.
- Implemented a six sigma approach to operating and problem solving sterilisation processes within the Irish facilities of Boston Scientific.
- Adapted lean manufacturing principles within the sterilisation processes creating greater efficiencies and operating capacities for routine processing
- Commissioned and validated State of art Microbiology labs at Boston Scientific, Vistakon and National Medical Care.
- Managed Biocompatibility programmes during R&D projects.
- Managed and engaged in numerous FDA, NB, TGA, Japanese and Chinese audits
- Performed audit preparation at many medical device facilities
- Completed R&D project in MIT, Boston with Genzyme



Contact Details

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Qualifications

BSc Biotechnology (Hons), DCU, Ireland
PhD in Genetics, Bristol University, UK

Consultancy Roles

- Technical and regulatory support to medical device companies during regulatory audits and responding to compliance issues.
- Development of Sterilisation strategies for new products using EO, Gamma and E-Beam technology
- Problem Solving
- Sterilisation/Micro training
- Supplier audits for clients
- Microbiology Projects
- Validation of Process Water systems
- Biocompatibility projects
- Internal audit support
- Development of Quality System Procedures
- Quality System design and implementation