



CONSULTANT & INTERNAL AUDITOR FOR MEDICAL DEVICES MANUFACTURERS

QUALITY MANAGEMENT

*Improving your working processes,
Increasing your management efficiency*

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TYPES OF MISSIONS

Part Time Quality Management

- ✓ Part Time Quality Manager
- ✓ Action plan management,
- ✓ Regulatory watch
- ✓ Management review (preparation and monitoring)

At the right time and rhythm for you

Consulting

- ✓ ISO 13485 compliance
- ✓ Optimization and simplification of your working processes
- ✓ Technical file writing
- ✓ Internal and subcontractors audits

A great operational experience at your service

Training

- ✓ Management of Quality system ISO 13485 : 2016
- ✓ European Regulation (UE) 2017/745
- ✓ CEE/93/42 Directive
- ✓ Internal auditor

Helping your teams to develop their skills in the medical devices field

LANGUAGES

- ✓ FRENCH
- ✓ ENGLISH

EXPERTISE

Quality Management

- ✓ Implementation and update of Quality Management Systems (QMS) acc. to ISO 13485
- ✓ Development of a "Quality culture" in all levels of your organization
- ✓ 10 years experience as a Quality Manager

Planning via Objectives and Process Improvement

- ✓ Project management, Result oriented planning (objectives vs realisations)
- ✓ Organization, simplification and optimization of supply chain workflows, resources and process
- ✓ Implementation and follow-up of appropriate key performance indicators (KPI)

International environment

- ✓ Interventions in Europe, Nord Africa, Asia (audit, consulting, training)
- ✓ Experience in short and long distance subcontracting

Team Management

- ✓ 18 years experience in the management of project teams and operational teams
- ✓ Development of good practices of management to develop awareness, motivation and Quality empowerment of the personnel

PROFESSIONAL LIFE

Since 2015	Independent Consultant in Quality Management	MNOPé management SAS
2007 2014	Quality and operations Manager	COBLENTZ SAS Manufacturer and distributor of medical devices for podiatry
2003 2006	Administrative manager	BIOKAR DIAGNOSTICS (SOLABIA group) Manufacturer of products for microbiological diagnostics
2001 2003	Customer Service Manager for Europe	IPEL SA (INTERNATIONAL PAPER group)
1996 2000	Project Manager – Information System and processes	Manufacturer of Aseptic beverage packaging

EDUCATION

- ✓ **Professionnal education:**
 - **Internal auditor** : ISO 9001:2015, ISO 13485:2016, European Regulation (UE) 2017/745, Directive CEE 93/42
 - **Certified Trainer for Adults**
 - **Continuing training in Quality and Medical Devices standards and guides** : ISO 9001:2015, ISO 13485:2016, ISO 14971:2019, EN 62366-1 :2015, ISO 10993-1, ISO 11137, ISO 11737, MEDDEV 2.7.1. Rev 4
- ✓ **Initial education:**
 - 1994: Master in International Business - *ESLSCA, Paris.*
 - 1989: High school degree in Mathematics & Physics