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Medical Device Approvals, Inc.  
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### **QUALIFICATIONS:**

- 12 years experience as a regulatory submissions manager.
- CRA experience for all aspects of device studies
- Extensive medical clinical background as Registered Nurse / Perfusionist.
- Excellent working knowledge of medical devices especially in the cardiovascular area.
- Ability to direct complex submissions from concept to approval/clearance status.
- Goal-oriented individual with strong leadership capabilities.
- Organized, highly motivated, resourceful and detail oriented problem solver.
- Proven ability to work in unison with team members.

### **Regulatory Affairs / Clinical Research Independent Consultant**

#### **EXPERIENCE:**

2002- Present

#### **Medical Device Approvals, Inc.**

Fairfield, IA

Executive and Founder: Independent regulatory and clinical research consultant offering:

- **Regulatory strategy development for USA and Europe**
- **Extensive experience with 510(k) submissions.**
- **Experience with IDEs and combination products**
- **Submissions project planning, implementation and submission**
- **Implementation and management of Quality Systems compliant with FDA QSR and ISO 13485**
- **Document preparation to comply with Design Controls**
- **Software Validation documentation**
- **Conduct audits to assess compliance with FDA Quality Systems Regulations and ISO 13485**
- **Clinical study protocol development**
- **Case Report Form development**
- **Monitoring plan review**



- **CRA / Monitoring services including:**
  1. **Routine monitoring for post-market approval registry for cardiac re-synchronization device indicated for heart-failure.**
  2. **Routine monitoring for pre-approval study for cardiac re-synchronization device**
  3. **Routine monitoring for pre-approval study for deep brain stimulation device.**
  4. **Site management and routine monitoring for pre-approval study for spinal technology.**

## **Previous Positions**

1998-2003

### **Jostra AG**

Hechingen, Germany

Submissions Manager: Developed regulatory strategies, test plans, and compiled submissions for all class II and III products. Functioned as liaison to FDA and worked closely with R & D engineers and product managers. Supervise submissions from subsidiary regulatory departments.

- Established U.S. Regulatory Affairs department.
- Defined departmental positions and responsibilities.
- Responsible for writing all 510 (K) and IDE submissions
- Submitted 12 class II submissions, 4 class III, in four years.
- Developed regulatory strategies for all device submissions to FDA.
- Acted as project manager for all U.S. regulatory submissions.
- Reviewed protocols of all submission related bench and animal testing.
- Key contact for all interaction with FDA including pre-submission meetings.
- Identified and provided all standards and guidance documents for device testing.
- Evaluated all changes to existing products for regulatory requirements.



### **Clinical / Management**

1989-1998

#### **Medical Center of Delaware**

Newark, DE

Chief Perfusionist: Manager of perfusion services in center performing 1200 open heart cases

per year; reported directly to hospital administration.

1978-1987

#### **Marquette General Hospital**

Marquette, MI

R.N./Charge Nurse/ICU/CCU: Advanced assessment of all types of critically ill medical/surgical patients. Preceptor for new employees.

### **Education :**

1972-1974 R.N. Gwynedd Mercy School of Nursing, Gwynedd Valley, PA

1987-1989 CCP. Clinical Perfusionist, Hershey Medical Center, Hershey PA

### **Professional Memberships :**

RAPS – Regulatory Affairs Professional Society

ACRP-Association of Clinical Research Professionals

## **In Depth Summary of Regulatory Education and Experience**

### **Regulatory Experience**

#### **Submissions:**

- Submitted multiple 510(K)'s for Class II and III disposable cardiopulmonary products including:
  - Oxygenators,
  - Heart-Lung machines,
  - Centrifugal pumps,
  - Catheters, Cannula,
  - Reservoirs and
  - Custom tubing circuits.
- Participated in design, testing aspects and then submitted 510 (K) for "Minimized" perfusion circuit.
- Submitted IDE for new procedure/therapy involving long-term respiratory support device with percutaneous catheter access



### **Clinical Research:**

- Developed and submitted clinical study protocol and case report forms involving 40 patients and several centers for a long-term lung support device.
- Developed clinical study protocols for device studies including In Vitro diagnostic devices
- CRF development
- Review monitoring plans
- Contract monitoring services for several Cardiac re-synchronization devices, Deep brain stimulation device and spinal device.

### **Continuing Education: Courses:**

- CRA Training by Medical Research Management ( 70 hrs. classroom + 2 Wks. "Hands On")
- Clinical Trials Design
- Good Monitoring Practices
- Investigators Guide to Clinical Research
- Project Management

### **Seminars:**

- 510(K) Submissions 101
- When to Submit a new 510(K)
- General vs. Specific Labeling
- Annual Device Submissions Workshops 2000, 2001,2002
- IDE / PMA Submissions 101