Kathleen Johnson, R.N. C.R.A
Medical Device Approvals, Inc.

Kathleen can be reached through
cdginc@clinicaldevice.com

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