



## **Regina Hart**

*Senior Clinical Consultant*

With over 18 years working in the medical device industry, Regina has gained significant experience monitoring clinical studies for medical devices, including heart valves, catheters, wound dressings and orthopedic products. She has also assisted with patient recruitment, collection of regulatory data for submissions and developing a network of sites and investigators. Regina's significant language skills - Dutch, German, English, French, Italian and Spanish - have also proved extremely important for managing cross border clinical studies.

### **EXPERIENCE:**

#### **Clinical Specialist /Project Manager**

Monitoring and organization of clinical studies for various medical device companies (heart valves, catheters, AAA repair devices, LVAD, CCO Catheter, wound dressings, kyphoplasty, extracorporeal membrane Ventilator, a device for advanced protective ventilation.

As Clinical Research Specialist:

- Site selection and monitoring of studies (incl. site initiation)
- Patient recruitment (independently setting up new system to recruit patient)
- Train Study Nurses to learn/improve ways of patient recruitment
- Setting up facilities in hospitals for patients to be interviewed by SN
- Case support (incl. product tracking)
- Organize meetings (within Europe, regional and within hospital) for GP's, or specialists to inform them about a certain study => patient recruitment
- Trouble shooter between investigator and sponsor

As Clinical Research Ass.:

- Monitoring
- Writing CRF's and designing studybinders
- Site Initiation visits and training of study nurses
- Effective tracking of trial progress and data quality
- Assistance in the collection of regulatory documentation in accordance with SOP's, monitoring guidelines and study specific requirements.
- Organization of a proper filing system of all relevant study documentation
- Interaction with the data management department and independent angiography core lab
- Interaction with EC's and hospitals



## **Regina Hart, continued...**

As Clinical "Consultant":

- Effective and timely communication with distributors and sites in Europe.
- Timely distribution of sufficient amounts of devices and other supplies to sites
- Organization of all transportation of devices from and to the manufacturer/hospital
- Organization of investigator meetings and training sessions.
- EC applications in Germany, Austria, Switzerland
- Writing reports about reimbursement of medical devices/medicinal products

### **TRAINING and CERTIFICATIONS:**

- ISW Course: Management Assistant, 1989 –1990
- ISW Course: Middle Management, 1999 – 2000
- Clinical Design Group inc. Course: Good Monitoring Practice, February 2002
- GCP, 2004,2007,2009
- Several in-hospital and in-company courses regarding automated patient-Files and product training, 2008 – 2009

### **EDUCATION:**

- European School, International Baccarauleat Bergen, The Netherlands, 1971 – 1978
- University of Amsterdam, Dentistry (foundation course), 1978 – 1980
- University of Amsterdam, German and Italian language and literature, 1980 - 1982

### **LANGUAGES:**

- Dutch
- German
- English
- French
- Spanish
- Italian