CTI Clinical Trial and Consulting Services

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**CTI Clinical Trial and Consulting Services named "Best Places to Work" in Greater Cincinnati for Second Consecutive Year**

**Upcoming Medical Meetings CTI will be Attending ...**

CTI will have a significant presence at upcoming medical meetings over the next few months.

**World Stem Cell Summit**
Pasadena, CA
October 3rd-5th

**Biotech 2011**
Philadelphia, PA
October 24th – 25th

**ACG 2011**
Washington, DC
October 28th – November 2nd

If you are interested in scheduling a meeting with CTI at one of these events, please contact Nick Schatzman at

# EMA Clinical Evaluation Reports

The European Commission Enterprise and Industry Directorate General has issued a substantially revised version of the MEDDEV 2.7.1 requirements for documenting clinical evaluation of medical devices, making the EU requirements essentially identical to those specified by the Global Harmonization Task Force (GHTF) in 2007. **The guidelines on clinical evaluation apply to new device introductions as well as to existing and already marketed devices.** They require medical device manufacturers to provide a Clinical Evaluation Report that shows how information in the medical literature supports the safety and use of the device:

- Identify the features of the device that require clinical data support;
- Identify available clinical data relevant to the device and its intended use;
- Evaluate each report in the literature in terms of its suitability for establishing the safety and performance of the device;
- Present conclusions about the clinical safety and performance of the device, based on the review of the medical literature.

In practice, these requirements usually can be met with a comprehensive review of the medical literature concerning the device in question and devices that are similar to it. It is important to note however that the regulatory authorities expect the Clinical Evaluation Reports described in the guidance to follow a specific format that enables them to determine if the conclusions of the report are adequate.

**CTI has provided Clinical Evaluation Reports of relevant medical**

513-598-9290 or via email at nschatzman@ctifacts.com

**Employee Update**

Please welcome the newest addition to CTI:

Linda Progelhof – Senior Clinical Safety Scientist

Congratulations to the following CTI employee recently promoted:

Jim Westerkamp – Senior Director, Consulting Services

**Quick Links…**

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**literature for several medical devices, including new launches, established devices, and periodic follow-up reports on devices for which we previously provided initial CERs.** Our reports have been accepted by the European regulatory authorities. Our process begins with a systematic search of the medical literature, according to a written protocol. The reports that are returned by that semi-automated search are then reviewed by a medical expert for relevance. Information documenting the key data in each report (authors, location, citation, patient population, study design, results) is placed in a user-friendly table, and each report is briefly summarized. The safety information is analyzed with respect to the device instructions for use, and conclusions regarding marketing of the device are spelled out.

In our experience, this requirement is very labor intensive for our sponsors. We welcome the opportunity to discuss an efficient process that will meet the regulatory requirements and minimize your time and efforts so you can focus on your products and customers.

*For more information contact:*

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CTI Clinical Trial and Consulting Services (CTI) is a unique drug and market development company offering a full range of services which encompass the entire lifecycle of drug development. These services include regulatory pathway design, clinical trial management, data analysis, medical writing, CME and training program development, market analysis and development and other consulting services. CTI focuses on the specific disease areas of solid organ transplant, hepatitis, infectious disease, end-stage organ disease and hematology/bone marrow transplant. With its combined expertise of clinical knowledge and market experience, CTI is uniquely positioned to incorporate both clinical and market driven endpoints and interpretations to provide extraordinary results.