Medical Writer for Medical Device Industry: Evolving Indispensable Role

The medical device industry is undergoing a surge in growth, with new products being developed and introduced into the market to meet the ever evolving, unmet needs of this industry. The medical writer in this industry performs a key role in facilitating this process. The key function of the medical writer is to analyze and present clinical and product specific data into accurate and regulatory compliant documents using standardized templates, and facilitate submission to the concerned regulatory authorities as part of the marketing application.

1 What are Medical Devices

The term medical devices cover a wide range of medical equipments used:

- To diagnose, treat and monitor diseases
- To alleviate or compensate for injuries and disabilities
- In clinical investigation
- In conception/pregnancy control
- To replace or modify an anatomical part (eg. artificial limb) or a physiological process (e.g. pacemaker)

2 Special Needs of Medical Device Industry:

Compared to the established pharmaceutical medical writing industry, medical writing for the medical device industry is still evolving. Hence, there are many challenges and needs specific to this industry:

- Medical devices are upgraded and undergo technological changes more often than pharmaceutical products, without the need for clinical trials to assess safety and efficacy.
- Some medical devices have evolved into becoming wearable devices that track a lot of personal information of the patient, which make them vulnerable to cyber attacks.
- Medical device writers play a key role in ensuring anonymization of patient data. This not only protects patient privacy, but also ensures patient safety from cyber-attacks and data misuse.
- Globally, there have been many safety issues associated with medical devices, such as, low durability with metal-on-metal hip replacement, rupturing of breast implants, and use of contaminated industrial silicone in breast implant.
- Illegal practices are rampant and result in unsafe and inferior products reaching the market. An example would be resale of used syringes through illegal re-processing and re-packaging.

Thus, the need to address new threats, new safety concerns and continuous scrutiny have resulted in new medical device regulations to protect the patients, and increased scrutiny before product approval. Regulation in medical devices is an evolving field, with many countries having no regulatory guidelines yet, while sometimes guidelines differ by zones within the same country. Hence, regulatory medical writers should have in depth knowledge of existing regulatory guidelines in any part of the world and keep abreast with changes.

3 Regulatory Guidelines: The Challenges

Currently, some countries only have established regulations for the medical device production facilities which just require Good Manufacturing Practice (GMP) certification, while others have stricter quality control guidelines for the devices themselves. However, since regulatory requirements are the same, an effort is being made to harmonize the guidelines through Global Harmonization Task Force (GHTF).

A few standard regulatory guidelines that can be referenced for medical device regulatory writing are:

Pharmaceutical Medical Writers Versus Medical Device Writers: Do They Need Separate Skill-Set?

Even though medical device writing is a relatively new field, the basic skill-sets needed for it are similar to that of the pharma writing industry. There is no prior requisite to have knowledge on medical devices or the technology behind it. Any medical writer in the drug industry can easily transfer his skills to write for medical devices.

In fact, senior medical writers in the drug industry can advise medical device companies on publication planning, documentation, regulatory and conference support.

Key skills: Experience and skills gained in pharmaceutical writing for evaluating data objectively and keeping a tab on guidelines and regulations will be relevant to medical device writing.

Similar Documentation: Both industries need similar documents like clinical study protocols, patient informed consent forms (ICFs), clinical study reports with lay summaries and Periodic Safety Update Reports (PSURS). (Only difference is the content!).

Exception: clinical evaluation report (CER) is a document used solely for medical devices

Publications: Medical device trials need to be registered just like drug trials and the results need to be published. As there are hardly any journals solely for medical devices, and so publications are presented for same journals as drugs, based on the disease area and follow the same guidelines such as GPP3 Guidelines, ICMJE Recommendations, CONSORT Statement etc.

Conference Coverage: Just like drug industry abstracts and presentations are required for major conferences irrespective of whether they are presented in device specific conferences (e.g. Transcatheter Cardiovascular Therapeutics and EuroPCR conferences), or in mixed conferences for both drugs and devices.

### Key Differences Between Medical Devices and Pharmaceuticals

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<tr>
<th>Parameters</th>
<th>Medical Devices</th>
<th>Pharmaceutical Products</th>
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<tbody>
<tr>
<td>Development</td>
<td>By engineers, using engineering technologies</td>
<td>By chemists, pharmacists, pharmacologists, life scientists</td>
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<tr>
<td>Development Cycle</td>
<td>Short, usually completes in 23 years so new devices hit market faster than drugs</td>
<td>Long, can take 10 years or more</td>
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<td>Clinical Trials</td>
<td>Clinical trials are not mandatory, if required is tested in small number of patients</td>
<td>Mandatory for drug approval</td>
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<td>There is no categorization in P1 to P3 as for drugs</td>
<td>Usually drug development has to go through Phase 1 to Phase 3 development before a drug can be filed for approval</td>
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<td>No healthy volunteer P1 trials so directly used on patients</td>
<td>Every drug is first tested in small group of healthy volunteers and then given to patients</td>
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<td></td>
<td>Feasibility, pilot, and first-in-human studies are similar to Phase II studies of drugs</td>
<td>Post-market and registry based studies are similar to Phase IV drug studies</td>
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<td>End User</td>
<td>Usually used by technicians and medical experts</td>
<td>Parenteral routes like intravenous, intramuscular, intrathecal, intratumoral etc are used by medical experts</td>
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<td>Patient use is restricted to wearable or assistive devices and diagnostic kits</td>
<td>Patients the primary end user for oral medications and most subcutaneous ones</td>
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<td>Effect on human body</td>
<td>Very few are used inside the patient’s body</td>
<td>Effect is influenced by patient factors like compliance, and by genetics and drug interactions</td>
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<td>The expertise of the operator and method of implant influence outcomes</td>
<td>All drugs enter human body so their effect is profound</td>
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<td>Structual Changes</td>
<td>Devices undergo frequent modifications and updates</td>
<td>The drug formulation once approved remains same throughout</td>
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<td></td>
<td>No trials are required to make these changes</td>
<td>New formulation will need to undergo new trials</td>
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However, the medical device writers should keep in mind some key differences between medical devices and pharmaceutical products:

- Medical equipment manufacturing companies are more focused on commercial activities than regulatory and publication related activities.

Overall, the medical device writing field is evolving, thus providing myriad opportunities to medical writers to work on various aspects of the field, without being restricted to certain responsibilities only. Well-established organizational structures and positions are still lacking. Medical device writers can, thus, grab this opportunity to create their own organizational structures and positions. Medical device writers can be the key guiding force in making the industry more streamlined and regulatory compliant.

### References


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