sintera inc.

Health Care Consulting

New Format for Product Monographs

Mandatory October 1, 2004.

Minimizing delays in the review of your PMs is important to us.

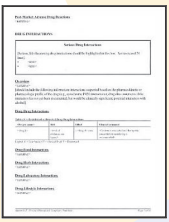
Simplifying complexity is our goal.

Contact Sintera and allow us to do both.

Product Monograph

New as of October 1, 2004

Health Professional Information



Scientific Information

Consumer Information

Let us help you successfully submit product monographs that comply with Health Canada's new guidance document and standard templates.

(Sintera offre ses services en français)

In 1997 Health Canada approached Sintera to develop a more user-friendly format for product monographs. Our expertise as health professionals and former editors of the CPS provided unique insight to the project.

We developed and validated the new format; drafted the guidance document; assisted with the consultation process and trained the reviewers to ensure standardization.

Health Canada now requires that the product monograph be broken down into three sections:

1. **Health Professional Information**
2. **Scientific Information, and**
3. **Consumer Information**

As you prepare your NDS, SNDS or Notifiable Change you will need to allow more time to:

- **Become familiar with the new format**
- **Develop a new PM using the guidance document**
- **Rework an existing PM to comply with the new format**

Let us help you meet these timelines and manage the transition to the new standards by providing:

- **in-house training**
- **product monograph quality assurance reviews**
- **consumer information drafts**

In-house training to quickly familiarize your staff with the new standards.

This will include training on format changes and highlight areas of significant change in the guidance document such as drug interactions and consumer information

- tailored to your company's needs
- working with your product monographs

Quality assurance reviews

The QA review will ensure the PM component of your drug submission meets the new format requirements. Health Canada reviewers will then be able to focus more on content rather than format, minimizing delays in the review time.

Draft consumer information

This now applies to all drugs regardless of administration setting (e.g. hospital use only, emergency) because the audience is the general public.

Reformat existing monographs

Rework existing PMs to comply with the new format. This includes drafting the consumer information for monographs that may not have this section.

We can supplement your resources with any or all of the above services to ensure you meet the October 1 deadline and retain staffing flexibility.

Sintera has the support of Health Canada to help you bridge the gap between the old and the new PM format requirements.

We will navigate your products successfully through this transition to the new format.

We don't want you to miss out on any of the opportunities we have to offer. Call us today. We will answer any questions you may have.

Contact Patricia Carruthers-Czyzewski or Louise Travill at 613-260-5385 or visit our web site at www.sintera.com

sintera inc.

Health Care Consulting

Specializing in pharmaceuticals

Applying our skills and experience to your projects

Client centered innovation