

# Pharmaceutical Documentation Monograph

## **Technical Writing, Pharmaceutical Writing | -**

Pharma Compliant Documents, LLC in Newark, New Jersey, extends technical and pharmaceutical writing services to clients worldwide.

<http://www.gmpdoc.com/>

## **Monographs | Pharmatec Consult -**

GMP-compliant documentation and testing; Filter Exchange; KI Discuss; Best Practice for Particle Monitoring in Pharmaceutical Facilities; Technical Monograph No

[http://pharmatec-consult.com/?page\\_id=348](http://pharmatec-consult.com/?page_id=348)

## **Scientific and Medical Writing Services -**

Scientific and Medical Writing we are able to prepare a diverse range of medical and pharmaceutical documentation to address the Product Monographs,

<http://www.intertek.com/pharmaceutical/scientific-medical-writing/>

## **General Opinion on Monographs - FIP - -**

FIP is the global federation representing three million pharmacists and pharmaceutical when applicant submits documentation for based on your monographs.

[https://www.fip.org/monographs\\_general\\_opinion](https://www.fip.org/monographs_general_opinion)

## **British Pharmacopoeia - Official Site -**

The British Pharmacopoeia 2015, the official source of British pharmaceutical standards. Produced by the British Pharmacopoeia Commission Secretariat of the Medicines

<http://www.pharmacopoeia.co.uk/>

## **FDA-CHPA Joint Presentation - ASQ -**

CHPA Guidelines on Stability Testing of OTC Monograph Drug Products all with appropriate documentation. Why Follow this Alternative Approach?

<http://asq.org/fdc/2005/06/chpa-guidelines-on-stability-testing-of-otc-monograph-drug-products.ppt>

## **Documentation in GMP (Good Manufacturing -**

Why Documentation is necessary in pharmaceutical industry Name of pharmacopoeia or any other recognized book of standards in which monograph appears or

<http://www.authorstream.com/Presentation/rhytm8910-1339055-documentation-gmp/>

## **Pharmaceutical Excipients, Raw Material Suppliers -**

Buy pharmaceutical excipients, raw material suppliers India, Comprehensive regulatory documentation support; Pharmacopoeia compliance to various monographs;

<http://www.qualityexcipients.com/>

## **Active Pharmaceutical Ingredient Specifications -**

Active Pharmaceutical Ingredient Specifications on Submission of Documentation for a Multisource General monographs and specific monographs are

[http://africa.unfpa.org/webdav/site/global/shared/procurement/08\\_QA/qa\\_resources/Mumbai\\_Workshop\\_Nov\\_4-7\\_2014/1-6a%20API%20Specification%20-%20CC%20Lee.pdf](http://africa.unfpa.org/webdav/site/global/shared/procurement/08_QA/qa_resources/Mumbai_Workshop_Nov_4-7_2014/1-6a%20API%20Specification%20-%20CC%20Lee.pdf)

### **United States Pharmacopeia - Official Site -**

USP's mission is to improve the health of people around the world through public standards and Pending Monograph Page Pharmaceuticals; Biologics

<http://www.usp.org/>

### **OEL Fastrac - Affygility Solutions -**

OEL Fastrac Catalog. Handling highly potent compounds? OEL Fastrac by Affygility Solutions is a convenient and affordable way for pharmaceutical, biotechnology

<https://affygility.com/oel/>

### **Monographs | CDMV, products and services -**

CDMV offers a comprehensive monograph in English and French for most pharmaceutical products for veterinary use. CDMV allows you to access the Canadian version of the

<https://www.cdmv.com/en/monographs.sn>

### **Chapter 4 Final 0910 - European Commission -**

EudraLex The Rules Governing Chapter 4: Documentation Legal basis for publishing the detailed guidelines: - The reference, if any, to a pharmacopoeial monograph;

[http://ec.europa.eu/health/files/eudralex/vol-4/chapter4\\_01-2011\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-4/chapter4_01-2011_en.pdf)

### **Monograph - Wikipedia, the free encyclopedia -**

A monograph is a specialist work of writing on a single subject or an aspect of a subject, usually by a single author. Contents 1 In academia 2 In library science 3

<http://en.wikipedia.org/wiki/Monograph>

### **The International Pharmacopoeia Overview -**

The International Pharmacopoeia Overview. Caroline Mendy Technical Officer - Quality Assurance and Safety: Medicines. Quality of Active Pharmaceutical Ingredients

<http://www.slideserve.com/Jimmy/the-international-pharmacopoeia-overview>

### **The PQG series of Monographs > -**

Click on the titles for a brief overview of the monograph s content: Pharmaceutical Premises and Environment Pharmaceutical Documentation Pharmaceutical

<http://www.pqg.org/pharma/publications/monographs>

### **HMPC Guideline on assessment of clinical S E -**

page 2/13 emea 2006 guideline on the assessment of clinical safety and efficacy in the preparation of community herbal monographs for well-established and

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003644.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003644.pdf)

### **Biowaiver Q&A - FIP - International Pharmaceutical -**

International Pharmaceutical Comments and new data to published Biowaiver Monographs can be posted when applicant submits documentation for variation

<http://www.fip.org/monographs>

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