



## Links to guidelines relevant for the MIND module:

Legislation – Introduction to the different guidelines:

### 1. ICH guidelines:

<http://www.ich.org/cache/compo/276-254-1.html>

### 2. EMA guidelines:

<http://www.ema.europa.eu/htms/human/humanguidelines/background.htm>

### 3. FDA guidelines:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

Science forum: Abstract database containing articles from FDA

<http://www.accessdata.fda.gov/scripts/oc/scienceforum/sf2006/search/search.cfm>

CFR – Code of Federal Regulations Title 21

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>

Dissolution Methods

<http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>

Drugs

[http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search\\_Drug\\_Name](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name)

Freedom of Information

<http://www.fda.gov/RegulatoryInformation/FOI/default.htm>

Inactive Ingredient

<http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>

Orange Book

<http://www.fda.gov/AboutFDA/CentersOffices/cder/ucm119100.htm>

Warning letters

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

#### **4. EP:**

<http://www.edqm.eu/en/Homepage-628.html>

Different technical guides:

<http://www.edqm.eu/en/Technical-Guides-589.html>

Technical guide:

[http://www.edqm.eu/medias/fichiers/Technical\\_Guide\\_for\\_the\\_elaboration\\_and\\_use\\_of\\_mon.pdf](http://www.edqm.eu/medias/fichiers/Technical_Guide_for_the_elaboration_and_use_of_mon.pdf)

Database of monographs:

<http://www.edqm.eu/en/Databases-10.html>

#### **5. USP/NF:**

#### **6. Other:**

WHO GMPguides:

[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/production/en/index.html](http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html)

Biologicals<areas of work:

<http://www.who.int/biologicals/areas/en/>

DLS:

<http://www.laegemiddelstyrelsen.dk/1024/visLSArtikel.asp?artikelID=15958>

DANAK:

[http://webtool.danak.dk/Plone/site\\_login/](http://webtool.danak.dk/Plone/site_login/)