100 HOT TOPICS FOR DISSERTATION FOR PG DIPLOMA/ DEGREE IN REGULATORY AFFAIRS

Mr. R.M. Gupta (M. Pharm.), is a free lancer consultant for US DMF, COS, ANDA, ACTD, CTD, eCTD and he is also the director of Global Institute of Regulatory Affairs, Pune. **He is also associated with Perfect Pharmaceutical Consultants Pvt. Limited (Pune, India) an organization providing regulatory solutions to Drug Industry for the last 25 years.**

Abstract: The Post Graduate education courses in RA generally require submission of a dissertation on some current topics in drug regulations. The quality of the dissertation indicates the knowledge and understanding of the subject matter.

This article is specially written to guide RA students for selecting the most current regulatory topic and to design a powerful dissertation on the same.

The students are s are invited to post their queries at guptarmg1952@gmail.com

INTRODUCTION

Post Graduate Training and Diploma in Regulatory Affairs is rising rapidly in India and abroad. Currently there are more than 100 Schools all over the world which imparts Post Graduate Diploma, M.Sc. or M. Pharma in RA. One of the major criteria for qualification RA is dissertation/course work/project profile of 10,000 to 15,000 words on a topic provided by the Course Director.

A good dissertation shall demonstrate that the student has understood the topic from all regulatory angles. It shall be supported by references to the peer reviewed articles from literature. It may also include References to the regulatory experts who were consulted by the student to understand the practical aspects of the subject matter.

The dissertation must be the original work of a single student.
The topic for dissertation shall be of current importance to impact the examiner
The students are advised to present the dissertation must in a clear and professional manner.

Once the submission is ready it shall be self checked by the student for the following points

CHECKLIST FOR REGULATORY DISSERTATIONS

1	If the cover pages presents the title of the presentation, version number and name of author and the date of final editing and the date of submission.
2	If the subsequent page presents the purpose of dissertation and acknowledgements to the contributors
3	If the detailed index is provided for the presentation
4	If all the sections and sub-sections are clearly written with ample white space?
5	Does the page layout, spacing, tabular presentation, graphical presentations look professional rather than like a simple typing job?
6	Does the presentation is visually pleasant?
7	If the presentation has polished appearance
8	If the generally acceptable fonts fonts such as such “Times New Roman” is used through out?
9	Are the design elements such as Tables, Graphs, font size, Font types, Bolding are used appropriately for easy reading and quick capturing by the eyes?
10	If there is good balance between text and white space?
11	Are margins even on all sides?
12	Are design elements like spacing and font size used consistently throughout the document?
13	If all the pages are properly numbered and captioned and the page breaks are formatted properly?
14	Are all sections clearly captioned?
15	Are sections placed in perfect order as detailed in CTD Guidelines?
16	If the submission is specific to the scope as defined by the course director?
17	Does the data indicate the appropriate compliance with current drug regulations?
18	Do the submission uses scientific and regulatory terminology?
19	Does the submission meet all regulatory guidelines and specifications?
20	If the content flow is logical and easy to understand?
21	If the dossier is as perfect as possible, with no careless technical, typo, spelling, grammar and syntax errors?
22	If the bibliography is presented in most scientific manner
23	Does the presentation includes authors own statements
24	Does the presentation provide suitable references for the text taken from standard books, journals and regulatory guidelines?

TOPIC FOR DISSERTATION WORK

It must be current, novel, creative and meaningful .Ideally it shall add value to the Regulatory Compliance. The selected topics may provide critical review and solutions to regulatory submissions. The followings are top most 100 topics for regulatory research and dissertation work.

100 TOPICS FOR REGULATORY RESEARCH AND DISSERTATION WORK

1	Similarities and Difference between US DMF, Canadian DMF and eDMF
2	Similarities and Differences in Approval procedure for New Drug Application in USA and EU
3	Comparative study of New Drug Application Procedure in US,EU and India
4	Recent Advances in Regulations for Labeling and Advertising in USA
5	Common Deficiencies in Regulatory submissions
6	FDA Review Procedures for NDA,ANDA and DMF
7	EDQM Review Process for CEP
8	Role of Post Approval Clinical Trials for Drug safety
9	Resources for scientific and technical information for designing Regulatory Submissions
10	Current Deficiencies in Schedule Y
11	Current Role of GMP Audit for Marketing Authorizations of API
12	Current Regulations for Marketing Authorization of Pharmaceutical Excipients
13	Current Regulations for Marketing Authorization of Pharmaceutical Packaging Materials
14	Marketing Authorization of New Drug substance in USA
15	Marketing Authorization of New Drug substance in Europe
16	Regulatory Guidelines for Product Development
17	Critical and Comparative Analysis of Marketing Authorization Procedures in Developing Countries
18	The Role of RA in Pharmaceutical Exports
19	Risks and Opportunities in Development of New Drug
20	Question based Review of Regulatory Compliance
21	Electronic Regulatory Submissions
22	Principles and Guidelines for Regulatory Affair of Pharmaceutical Products
23	Conflicts and Solution Trends in Regulatory issues
24	Challenges and Prospects for filing CEP in Europe
25	Standard Practices in Regulatory Compliance
26	FDA 483 Notifications
27	Challenges in Regulatory Filings for Generic Products
28	Current Regulations for Herbal Products
29	Current Regulations for Biological Products
30	Role of ICH in Harmonizing Drug Regulations
31	Regulatory System in ICH Region
32	Regulatory System in ASEA
33	Regulatory System India
34	Latest Regulations for BE studies for the approval of ANDA
35	Current trends in Regulatory Actions against Misbranding and Adulteration
36	Design and development of National Drug Regulatory System and Policies
37	US Drug Regulatory System v/s European Drug Regulatory Systems
38	Challenges in designing ANDA for Parenteral Products

39	Challenges in designing CEP on Anticancer Products
40	Challenges in drafting CTD Module 2 (Clinical and Nonclinical Summary)
41	Strategy for Regulating Regulatory Functions
42	Role of Regulatory Affairs in Marketing Pharmaceutical products
43	Regulatory strategy for filing NDA/ ANDA
44	Regulatory strategies for successful pan-European registration
45	Strategic Planning for Regulatory submissions
46	The effective strategies for interactions with Regulatory Agencies
47	The commercial aspects of regulatory approvals
48	Electronic Common Technical Document submissions
49	Interrelationship between Regulatory Affairs, Quality Control and Quality Assurance for regulatory submissions
50	Regulatory issues for import of Pharmaceutical Products into India
51	Regulatory issues for export of Pharmaceuticals products to Latin America
52	Regulatory issues for export of Pharmaceuticals products to countries under ROW
53	Malpractices in Regulatory Submissions (MRS)
54	ICH Guidelines for Impurity Profiling
55	Role of Training in Regulatory Compliances
56	Principle of Regulatory Compliance (PRC)
57	Market authorizations in Latin America
58	Life Cycle of Drug Regulations (LCDR)
59	Latest Trends in Regulatory Compliance Training
60	Current Trend in Liaison with Regulatory Authorities
61	Current Trends in Regulatory Projects Management
62	Regulatory Aspects of Contracts Manufacturing
63	Pharmacopeial Standards for API
64	Current Trends in Review of CTD Dossiers
65	CEP Project Management
66	Mutual Recognization Procedures (MRP)
67	MAA Project Management
68	Product Registration Strategies
69	Current Appraisal Procedures for New Regulations, Standards, Policies, and Guidance issued by Regulatory Authorities
70	Current Trends in Planning, Preparation and Delivering Regulatory Submissions
71	Current Regulations for Variation Filings for the registered products
72	Good Practices in Evaluation and solutions to the deficiencies in CTD Submissions
73	Good Practices in updating Regulatory Filings.
74	Current Trend in follow-up procedures with MOH for the registration of Pharmaceutical products
75	Current Regulations for labeling and Advertising of Medicinal products
76	Good Practices for the Management of Quality Audits conducted by Regulatory Authorities
77	Good Practices in Management of comments/deficiencies in CTD/ACTD
78	Knowledge Management in RA (KMRA)
79	International Regulatory Framework (IRF)

80	Review and Approval Procedures for Promotional Materials
81	Regulatory Practices in CIS Countries
82	Current Regulations for Clinical Trials
83	Role of COPP in Pharmaceutical exports
84	Risk Analysis of Regulatory Non Compliance
85	Current Compendia Standards for Drug Products
86	Current Compendia Standards for API
87	Review of Responsibilities and Expectations from RA Professionals
88	Self Audit procedures for Regulatory Compliance Issues
89	Latest trends in Archiving of Regulatory Submissions
90	Corrective and Preventive procedures for Regulatory Compliance
91	Review of Regulatory Guidelines available on Web
92	Review of Free Regulatory Knowledge Resources on Web
93	Current Practices in Solving Complex Regulatory matters
94	Trends in the Management of Relations with Health authorities
95	Role of QMS (Quality Management System) for effective Regulatory Compliance
96	Master Regulatory Compliance Program (MRCP)
97	Recent Developments in Regulatory Compliance Strategies,
98	FDA Litigation Procedures for Regulatory Noncompliance
99	Annual Regulatory Compliance/Noncompliance Review Procedures
100	Trends in designing chemistry, manufacturing and controls (CMC) components of regulatory submissions
101	Recent trends in Training Regulatory Project Team Members, Cross functional teams, Senior management and Regulatory consultants associated with the company.
102	Patent issues in ANDA Approval
103	Good Practices in Organizing Regulatory Compliance Projects
104	Management of NC Reports /Queries issued by MOH
105	Review of the Current Status of Schedule Y
106	Good Regulatory Compliance Practices (GRCP)

ASSESSMENT OF DISSERTATION AT GIRA

The overall aim of the dissertation is to train the student for deep understanding of the regulations to resolve complex regulatory problems most economically, rapidly and to the full satisfaction of the regulatory authorities Assessment o**f** dissertation is a complex affair. At GIRA all dissertation are critically checked for presentation and basic understanding of the project by a Primary Regulatory Expert and by Course Director. Please refer the Annexure for the format used by GIRA for dissertation assessment.

CONCLUSION

Dissertation writing is a critical element for Graduate/Post Graduate Course in RA. Dissertation is an evaluation of Intelligent Quotient and Regulatory Knowledge of RA students. The topic for the dissertations shall be of current importance and the presentation must display deep understanding of the relevant regulations.

Note: For any help on dissertation design, writing and evaluation please contact the author

Rajkumar M. Gupta

Managing Director- Perfect Pharmaceutical Consultants Pvt .Ltd
Director-Global Institute of Regulatory Affairs (GIRA)
Drug Regulatory Affairs Consultant and Regulatory Affairs Trainer
(CTD, eCTD, DMF,CEP, ANDA Designer and Reviewer)

Regd. Office: - Prestige Classic (D Wing)
Dawa Bazar, Pune Mumbai Express Highway,
Chinchwad, Pune 411019, Maharashtra, India.

Contact Mobile No.:- +91-9371020504
E-Mail:- guptarmg1952@gmail.com
Web: www.regulatoryinstitute.com
Article Links - https://sites.google.com/site/ppcdmf/announcements

APPENDIX

DISSERTATION EVALUATION FORM AT GIRA

(Subject: _____)

No.	Parameter	Marks Allotted	Primary Evaluation	Secondary Evaluation
1.	**Presentation**	**15**		
	- Proper Index/ Numbering/ Printing Layout	5		
	- Use of Diagrams/ Flow charts	5		
	- Grammatical Errors	5		
2.	**Content**	**20**		
	- Technical content covered	10		
	- Depth of information	5		
	- Correctness/ Relevancy of the information	5		
3.	**Referencing**	**10**		
	- Proper referencing	5		
	- Use of own language	5		
4.	**Creativity/ Overall Conclusion**	**5**		
	Total	**50**		

Result (Average): /50 – (grade)

A Grade	**≥ 40 /50**
B Grades	**30 – 40 /50**
C Grade	**20 – 30 /50**

Date and Sign and Comments by of Primary Evaluator
Date and Sign and Comments by Secondary Evaluator

