60 TIPS TO BECOME A GOOD REGULATORY EXPERT

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He is associated with Perfect Pharmaceutical Consultants Pvt. Limited and Global Institute of Regulatory affairs (Pune, India). He is dedicated solely to regulatory profession. This article is solely written to guide, educate and train regulatory community at large.

This article is based self experience of 25 years of the author

Abstract: Regulatory affairs is an advanced and complex science involving highest degree of Pharmaceutical, Scientific, Clinical, Non Clinical and Chemical and Regulatory knowledge as designed by bodies such as ICH, PICS ,US FDA, EDQM, EMEA,WHO and UK MHRA .

It is extremely difficult to expertise in all the segments of RA. This article is written to guide the fresh and young RA professionals to excel in regulatory submissions and mitigation of regulatory queries.

This article is based on self experience of 25 years of the author.
The readers are invited to post their queries at guptarmg1952@gmail.com

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1. Read regulatory updates on US FDA, EDQM and ICH and other regulatory websites daily. Subscribe to automatic updates facility at US FDA site. Subscribe to Free Pharmacopeia forum published by FDA

2. **Be** serious about regulatory tips you get from visiting regulatory experts, FDA investigators, GMP auditors, QC/QA experts

3. See your regulatory submissions as a craft. See that ….

- No information (critical/non critical) is missing in regulatory document ready for submission.
- Important graphs, figures, tables, full text PDF articles are properly embedded in the text.
- All Info is relevant and up-to-date with current FDA/EDQM/ICH Guidelines and Pharmacopeia monographs.
- Spell check and grammar is perfect,

- Margins, spacing and alignment is perfect
- Bibliography/References are provided
- Abbreviations are explained
- If previous submission is used as template for the next submission, than check info is properly customized. The information of the previous product shall not appear in the info of the next product.

4. Design the submission for zero queries but prepare yourself to any query which may be raised. As per the experience of the author even the best submissions evoke serious queries.

5. Keep a complete record of your submissions. Please check that the record provides date of first submission, renewals, amendments, variations, and withdrawals to the actual.

6. Read Regulatory Guidelines regularly. Every time you read the guidelines, you will learn something new. Prepare notes of important learning.

7. Plan a yearly/six monthly or quarterly schedules for your submissions.

8. Know and master at least 5 critical priorities of regulatory submissions.

9. Say no to deviations/manipulations.

10. Keep in touch with regulatory professionals.

11. Improve your regulatory reviewing/documenting skill every single day.

12. Get a regulatory affair mentor and keep in touch with him.

13. Attend regulatory webinars/seminars frequently.

14. Review complicated and complex new regulations.

15. Keep your self mentally and physically healthy. Avoid too much stress of continuous reading and writing

16. Find heroes in Regulatory affairs and follow them

17. Be a hero to your regulatory colleagues.

18. Smile at upcoming regulations and master them.

19. Be the most ethical person in documentation and representation of your company to FDA

20. Don't settle for anything less than perfect compliances to all the regulatory clauses defined in CTD/ACTD.

21. Derive pleasure from new and challenging regulatory filings.

22. Save important regulatory learning's on your desktop.

23. Spend time to relax. Do not work continuously. Relax completely on weekly holidays.

25. Write thank you letters to those who've helped you or solved your regulatory problems

26. **Avoid people who are always confused with regulatory norms.**

27. Remember that regulatory writing is about explaining the facts scientifically in a simple language. Do not use complex text and figures which may be interpreted wrongly.

28. Always create strong impact on your colleagues/regulatory authorities with regulatory presentation

29. Have at least 5 great regulatory affairs expert as your friends.

30. Be polite, precise and to the point in all your communication with regulatory authorities. Never try to contradict with them instantly. The regulatory authorities have experience of dealing hundreds of people like you. They are seldom wrong.

31. Concentrate only on regulatory review/writing when at work. Don't allow any distraction even if he is your boss. Keep away all distractions during work.

33. Read regulatory news on the internet or on subscribed journal daily.

35. Be patients with the knowledge you have .The regulatory knowledge is very vast and you cannot master it instantly. It takes its own time to mature.

36. Dream your position and knowledge level in Regulatory affair and pursue your dreams.

37. Be authentic in all regulatory functions.

38. You shall be passionate. Do not rush. Do not mislead your organization through Hatch Patch work.

39. Admit your error and rectify it when you know you should.

40. Never miss a moment to celebrate your successful regulatory submissions.

41. Have a vision for your regulatory position. You can dream to be regulatory affairs Director/President of a company or regulatory expert for FDA/ICH Body

42. Know your strengths and weakness in regulatory documentations. You must know the part of CTD in which you are an expert and in which part you are weak

43. Focus your mind on the good versus the lacking

44. Be patient. If you do not understand a query read it again and again. If you still do not understand it , take a break and read next day
If you still fail consult your seniors. If you're senior also fails to explain directly contact FDA

45. Don't give up. Every regulatory query can be resolved. Allow sufficient time and apply proper intelligence. Read the topic carefully or discuss with your colleagues to resolve.

46. Keep you PC clean and well organized. Store your raw data and final drafts separately. Provide date and version numbers to each draft. Maintain all the versions. Keep outdated draft separately. Ensure that your PC can not be accessed by no one else than by you. Employ change control system to ensure data integrity. Do not allow unnecessary data migration

47. Use scientific words and short sentences in all your documents.

48. Copyright your important drafts.

49. Read "As You Think".

50. Honor your commitments to your boss and to the customers.

51. Thank your subordinates who assist you in reference work, editing, copying, formatting, Drawing and preparing charts/ graphs/tables

52. Be a great teammate. You can not do every thing at one time. You need support from upper level as well as lower level and from external agencies

53. Give no energy to critics. Be prompt. Do not discuss unnecessarily about your Personal assignment with your colleagues

54. Regulatory documentation requires extensive reading and writing. Take off from the work as necessary

55. Know your top 4 values such as good knowledge, good grasping, good drafting and sincere working.

56. You shall be result oriented. Do not be just busy. Your work shall be productive and time bound to meet deadlines

57. Be Innovative

58. Speak less. Listen more. Read more. Document precisely and discuss when necessary.

59. Be like the best regulatory person you know in your life.

60. Make your assignment carefully and intelligently.

61. Expand your Academic Qualification by subscribing to various full time/ online/correspondence course offered by regulatory agencies and regulatory consultants.

Conclusion:

To become regulatory expert up-to-date knowledge of health regulations is the must. Further he shall have practical knowledge of drug manufacturing quality control and clinical trials.

*The author is associated with **Global Institute of Regulatory Affairs (GIRA)** which offers full time/part time/and correspondence courses in Regulatory affairs.