



Suggested format for recording your Lifelong Learning activities in the next 6 months

Date completed	Time taken (hours or minutes)	What did you want to learn to be able to do	Which area of your competences does this relate to?	How did you achieve your learning?	Describe how you were/will be able to apply your new learning
28/02/2008	7	As a new person to Regulatory Affairs, learn more about post approval maintenance procedures	Human Medicines – Regulatory Competences: Knowledge and application of registration procedures in Europe (Centralised, Mutual Recognition, Decentralised) for MA approvals, variations, extensions and renewals	Attend TOPRA CRED-Life Cycle Management: Regulatory Maintenance Activities	To maintain and also to suggest to management how existing MAA's may be improved
8/05/2008	5	Learn about new UK variations procedure in UK	Human Medicines – Regulatory Competences: Knowledge and application of registration procedures in Europe (Centralised, Mutual Recognition, Decentralised) for MA approvals, variations, extensions and renewals	Attend the MHRA coordinated BROMI day	To maintain existing MAA's by variation in UK
13-18/04/2008	42	To obtain a broad appreciation of EU Regulatory Affairs from development, through approval of MAA and onto maintenance.	Human Medicines – 1. Regulatory Competences: Knowledge and application of registration procedures in Europe (Centralised, Mutual Recognition, Decentralised) for MA approvals, variations, extensions and renewals 2. Knowledge about the discovery and development of pharmaceutical products	Attend TOPRA Spring Regulatory Affairs Introductory course	Better able to contribute to Eu project teams and provide regulatory input



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29/04/2008	4	Research registration procedures	Human Medicines – Knowledge and application of the registration procedures in other markets as appropriate for approvals, changes and updates	Research on Internet	Applying the procedures to registration of new products in new markets and providing summary within department to regulatory colleagues
03/07/2008	6	Find out more about requirements for SmPC's, PIL's and labelling	Human Medicines -Knowledge and application of requirements for information for promotion, labelling (SPC, PIL, user acceptance testing, Braille labelling)	TOPRA CRED module on SmPC, PIL and labelling	Able to interpret labelling requirements more effectively for manufacturing department
4 /08/2008	5	Improve my effectiveness in project teams	Soft Skills': Team working in a global environment	Institute of Biology Improve your Teamwork	Better able to appreciate the different roles people take within teams and use this knowledge to improve regulatory input to teams