Work package number	3	Work package title	Quality plan of the PHAR-QA project and consortium

Work package type	Management Implementation (the substance of the work planned including production, testing, etc) X Quality Assurance (quality plan) Dissemination Exploitation of results

Start *Month number*	1	End *Month number*	36	Duration *in number of months*	36

Description of the work package (limit 3000 characters)

In project management, QA requires the project manager and the project team to inspect the accomplished work to ensure that it is aligned with the proposal. For this PHAR-QA will have a dedicated QA team (P9/UMFCD) which will work on WP QPLN together with P2/PCN.

Basic "rubber stamp" QA principles (based on documents such as those of the U.S. Department Of Health And Human Services Food And Drug Administration, Title 21, Food and Drugs Chapter I: Part 58 Good Laboratory Practice For Nonclinical Laboratory Studies. Final Rule published in the US Federal Register 52: 33768–33782, September 4, 1987 (http://www.fda.gov/RegulatoryInformation/Dockets/FR/default.htm)), concerning the assurance that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with predefined regulations will be applied. Albeit WP QPLN will go further than this and apply the grip / build / engage model developed by A.B. Jones in Princeton (*Qual. Assur. J.*, 2009; 12: 132-138 and 2011; 14: 18-26).

In any project 10% of events account for 90% of results, and 90% of events for 10% of results. The aim of WP QPLN is to identify and monitor the 10% of events that produce results.

WP QPLN will use and refine some of the tools and techniques (essentially Excel spreadsheets) developed in PHARMINE WP6 / QPLN (http://enzu.pharmine.org/media/filebook/files/WP%20Final%20report%20-%20quality%20assurance%20in%20pharmacy%20education%20and%20training.pdf)

P9/UMFCD will be the lead on WP QPLN.