

Qualified Person Learning Programme Development: An Example of the Tempus Joint Project Activity

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The role of Qualified Person (QP) is a pivotal one in Quality Assurance within the pharmaceutical industry. The competences required are usually achieved through work experience and more formal forms of learning, such as postgraduate MSc and/or relevant short-term courses.

The aim of this work is to provide an example of an outcomes-based interactive approach to curriculum development performed through an international joint-project collaboration activity. Duties of QP in the pharmaceutical sector in Serbia used to be performed by expert pharmacists with the relevant industrial experience and a Postgraduate Specialization Degree in Drug Analysis and Quality Control. However, it has been recognized that the learning needs of QPs should be extended to include knowledge of drug formulation and manufacturing processes. Taking into account the pre-accession status of Serbia, harmonization with EU practice and policies has been emphasized. In particular, compliance with EU directives 2001/82/EC and 2001/83/EC, which detail the role of, and academic qualifications required by a QP will be necessary. In order to respond to this need which has been highlighted within the sector, the Faculty of Pharmacy, University of Belgrade (FP) took responsibility for establishing the relevant postgraduate course, and set this as one of the priorities of the current Tempus PQPharm Project.

An outcomes-based active learning approach to curriculum development and delivery has been devised with five elemental steps involving identification of learning needs, content design, learning activities planning, assessment and feedback.

Identification of learning needs and the desired learning outcomes was established through the collaborative efforts of the FP academic staff and experts from the Ministry of Health, Drug Agency and Pharmaceutical Manufacturers Group Council. Relevant curricula from a number of EU Universities have been examined and a number of brainstorming sessions held in order to design the appropriate educational content. Modular curriculum design has been accepted with a number of core and elective modules. Common modules have been identified linking the existing postgraduate courses. Curriculum content, learning and assessment activities will be designed through the intensive collaboration and exchange with Trinity College Dublin, University of Greenwich and University of Ljubljana.

Academic staff and industrial pharmacy professionals will work together to design flexible learning materials, activities and resources in their area of expertise. Pilot course implementation is planned and is expected to provide valuable feedback that will contribute to refinement of the proposed curriculum.

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