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TRAINING FOR THE QUALIFIED PERSON

HUNGARY 1995/6

FINAL REPORT FROM MODULES 1-4

UNIDO CONTRACT NO: 95/119/AV

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1. INTRODUCTION

David Begg Associates (UK) have provided four training modules (each of one week duration) to representatives of the Hungarian Pharmaceutical Industry, the Institute of Pharmacy (Inspectorate) and the Academia (University). The training covered:-

Module One - Law and Administration
Module Two - Quality Management, GMP and the Qualified Person
Module Three - Pharmaceutical Formulation and Processing
Module Four - Manufacturing Process Control and Validation

This report is to provide feedback from the perspective of the trainer and also to provide an overview of the QP model as it operates in the UK situation. The topics discussed are as follows:-

- The UK Model - Qualified Person Training Syllabus
- Typical Qualified Person Training Course in the UK
- UK Study Guide - Training Requirements
- Feedback from Hungarian Modules One to Four
- The Professional Role of the Qualified Person in the UK
- The Future

2. THE UK MODEL - QUALIFIED PERSON TRAINING SYLLABUS

The European Union legal basis for the requirement to have a Qualified person is European Commission Directive 75/319. This sets out the minimum academic qualifications and experience required to become eligible to act as a Qualified Person. Our report for subcontract S1 describes the situation in detail but basically the candidate must hold a relevant scientific degree plus have up to two years industrial experience. This has largely been interpreted in the EU as requiring a pharmacist but the UK has published a study guide and it is common for non pharmacists to gain eligibility.

Initially control was solely by the UK Government (Medicines Control Agency) who approved (or otherwise) nominees on Manufacturers Licences. Transitional arrangements were allowed initially and eligibility was given to those already performing the job of a Qualified Person.

Now, in the UK, there is a Study Guide and Guidelines on the requirements for practical experience. Eligibility is judged by the three professional bodies (Royal Pharmaceutical Society of Great Britain, Institute of Biology, Royal Society of Chemistry). There is no requirement that candidates apply for consideration as a Qualified Person after having completed any specific course. Some post graduate courses are recognised by the professional as fulfilling the scope of the Study Guide however. Eligibility for nomination on the Register of Qualified Persons is judged by an interview (lasting approximately two hours) by a panel of representatives from each of the Professional Bodies, who themselves are experienced in the industry (generally they are Qualified Persons).

The final approval to act as a Qualified Person is granted by the MCA/Local Medicines Inspector as it is a legal requirement in the UK that the Qualified Person(s) are nominated on the site Manufacturers Licence. If the Medicines Inspector feels that the experience/training of the nominee is inadequate he/she can withhold approval. This system of first judgement of eligibility by the profession followed by final approval being granted by the inspector is working well in general.

As recommended in the EC Directive 75/319, there is now a professional Code of Conduct for Qualified Persons in the UK. Failure to act responsibly or in an unprofessional manner can lead to disciplinary action by the professional body concerned. (The first sanction available to the MCA is suspension and subsequent removal of the nominee from the Manufacturer's Licence). This Code of Conduct includes a requirement for continuing professional development to ensure that the Qualified Person keeps abreast of current thinking/technology etc.

3. TYPICAL QUALIFIED PERSON TRAINING COURSE - UK MODEL

Most courses on offer in the UK are based around the UK "Study Guide" for Qualified Persons. They vary in length from 500 hours of training (plus projects) to over 1200 hours of training (plus projects) and extend over a period of two years.

In our experience, tuition **must** be combined with relevant practical experience throughout a Pharmaceutical Manufacturing facility. This practical experience is called for in the guidelines (issued by the professional bodies) but to ensure that the trainee Qualified Person is fully conversant with processing it must be carefully planned and co-ordinated to ensure maximum effectiveness.

No single UK degree meets the full requirements of the Qualified Person training. Pharmacy provides the best foundation but lacks or requires additional training in some areas (eg. Quality Management, Bulk Pharmaceutical Chemicals, Microbiology).

The modules/topics required in the UK Study Guide are as follows (each being between 20 and 120 hours study):-

- Law and Administration
- Medicinal Chemistry
- Formulation and Processing
- Microbiology
- Management
- Bulk Active Ingredients and Biopharmaceuticals
- Mathematics and Statistics
- Analysis and Testing
- Packaging and End Product Use
- Responsibilities of the Qualified person, Quality Management and the QP

4. FEEDBACK FROM MODULES ONE TO FOUR IN HUNGARY - A TRAINERS PERSPECTIVE

David Begg Associates provided a model which enabled delegates from industry, academia and the Hungarian Inspectorate to experience what a typical training module would include. The delegates were more mature and experienced than would normally attend Qualified Person training. This enabled the speed and intensity of the training to be higher than would be appropriate for normal candidates.

In view of the distance/travel costs David Begg Associates carefully chose two tutors for each of the Hungarian modules to suit the topics concerned. Our wide experience in the pharmaceutical industry and our extensive training resources enabled the courses to be successful. If a course is presented in Hungary from local resources, then more tutors would be required although there should be a continuous presence of at least two tutors to provide continuity at each module.

The was no formal assessment examination after each of the modules. We would recommend that assessment is included in any future locally organised modules.

The training style that we used was participative and included teamwork groups to consolidate learning and to stimulate debate/discussions. Qualified Persons require judgement in their day to day function and this aspect cannot be achieved by lectures alone.

5. TOPICS FROM MODULES ONE TO FOUR THAT REQUIRE FOLLOW UP

The topics requested by UNIDO to be covered in the four week period were numerous and would normally require much more time. Hence some topics were covered as requested but stimulated great interest in the delegates. Areas where additional depth would be advantageous are:-

- Management Skills/Techniques (especially personal and interpersonal skills) - all delegates
- Medicinal Chemistry - especially non-pharmacists in the attendee group
- Statistics applied to Pharmaceutical Processing - all delegates
- Processing - hands on experience of processing would be of great advantage to some delegates (eg. those with principally laboratory background)
- Quality Management/Quality Systems - there is still a Quality Control/Quality Compliance bias in some areas of the industry

6. TOPICS NOT COVERED IN MODULES ONE TO FOUR

For the attendees on Modules One to Four the following topics were not covered and would be advantageous (to some or all of the delegates):-

- Microbiology - applied microbiology related to pharmaceutical processes
- Bulk Active Ingredients/Biopharmaceuticals
- Packaging and End Product Use
- Analysis and Testing - this is particularly relevant to non-chemists. Resources in Hungary in this aspect are good and may benefit from a locally prepared course

7. THE PROFESSIONAL ROLE OF THE QUALIFIED PERSON IN THE UK

Awareness of the professional role of the Qualified person in the UK is generally not very high at present, Senior Management are just beginning to understand the role and also the value/benefit of the training for Qualified Person status. Many Qualified Person candidates, after having experienced the benefits of training/development are rising to managerial positions in their companies. The QP training syllabus is also of benefit to technical managers in general not just to the Qualified Person.

The training of the Qualified Person must be wide enough to understand the large variety of processes and testing involved in manufacturing. Additionally, it must also be sufficiently detailed to be credible.

The Qualified Person must combine technical skills with personal skills to be successful. These include:-

- Communication
- Leadership
- Teamwork
- Good Judgement

To enable this balance to be achieved, theoretical training alone is not enough (eg. distance learning courses in the UK are generally less effective). Training needs practical experience and projects.

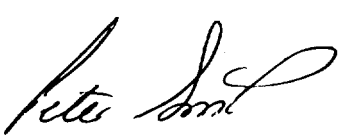
Overall the success of the Qualified Person concept relies upon a team approach to the design, implementation and control of the situation. The ideal team includes the Industry itself (including trade associations), Regulators/Inspectors, Professional Bodies and Academia. Additionally training never stops - continuing professional development is needed.

8. THE FUTURE

The concept of the Qualified Person is gaining world-wide interest. Additionally Hungary is gaining a good international reputation in pharmaceuticals. The Qualified Person initiative in Hungary will be a valuable contribution, especially if it is combined with good science and Quality Systems/TQM initiatives.

At present, debate is occurring to define a suitable model for the legal and professional role of the Hungarian equivalent of the Qualified Person. This should be encouraged, in our opinion, to enable proper control of medicinal product manufacture to occur.

We thank UNIDO, the Hungarian Government and the Hungarian Industry for allowing David Begg Associates to contribute to this project.



Signed **Date**

Peter Smith
Partner
David Begg Associates

24 June 1996