INTRODUCTION

The pharmaceutical industry in Malta has flourished in such a way to become an important contributor to the country’s economy. Malta’s legal and regulatory framework and later on its membership in the European Union (EU) have led to an increase in Malta’s pharmaceutical activities.¹

AIMS

To determine the potential deliverables of a pharmaceutical mini-scale production facility in Malta; to plan and design such a facility as part of a pre-design study; and to draw up estimates of the capital investment involved in such a project.

METHODOLOGY

Phase 1—Market Analysis: Preliminary communications were carried out with the identified local generic oral solid dosage (OSD) facilities in order to benchmark the objectives of the project. Semi-structured interviews with the major pharmaceutical stakeholders (Malta Enterprise and Medicines Authority) were conducted and questionnaires were also conducted amongst the 5 local generic OSD pharmaceutical companies.

Phase 2—Planning: A literature review was carried out. The Good Manufacturing Practice (GMP) guidelines related to the production of medicinal products for human and veterinary use² and studies carried out by Brocklebank et al.³ and Yu et al.⁴ were related to OSD facility layout and design were consulted. A multi-disciplinary panel of experts was assembled for the purpose of the study.

Phase 3—Design: Once the project scope and boundaries were determined, the layout of the facility was designed using AutoCAD 2011 and was validated by the panel of experts assembled for the purpose of the study.

To determine the potential deliverables of a pharmaceutical mini-scale production facility in Malta; to plan and design such a facility as part of a pre-design study; and to draw up estimates of the capital investment involved in such a project. The facility shown in Figure 1 is a standalone multi-purpose, non-sterile, OSD facility in which the active pharmaceutical ingredient (API) is to be processed under current GMP.

The building footprint is 2647m². For the purpose of the study it was assumed that the facility does not cater for the processing of highly potent and/or light-sensitive ingredients.

The facility can be divided into the classified zone consisting of the clean corridor and process rooms and the unclassified zone including the technical corridor, stores and auxiliary building. The air lock rooms act as buffer regions between the two zones. The logical arrangement of the process rooms ensures unidirectional flow of material so as to avoid product mix-ups and cross-contamination. The main process to be carried out in the facility is outlined in Figure 2.

The plan developed in the study explores the different potential outcomes of a mini-scale OSD facility and is based on standard, non-sterile, OSD facility in which the active pharmaceutical ingredient (API) is to be processed under current GMP.

To arrive at an estimate of the FCI, the cost of the delivered process equipment was used as the basis for the rest of the process-plant components. The delivered equipment cost amounted to approximately: €2,300,000. This value was assigned a percentage of FCI equal to 30% and includes the price for the main process equipment, documentation required, setting up of the equipment, packaging and transport. The cost associated with the rest of the process-plant components were based on expert advice. Taking into account all the process-plant components, the FCI cost estimate amounted to approximately: €8,400,000 (±30%).

RESULTS AND DISCUSSION

The potential deliverables identified during the market analysis are: research and development (R&D), manufacturing and quality control (QC), repackaging and micronisation as well as training and education.

Figure 2: Main process flow diagram for the production of uncoated tablets and hard gelatin capsules

CONCLUSION

The pharmaceutical industry in Malta has flourished in such a way to become an important contributor to the country’s economy. Malta’s legal and regulatory framework and later on its membership in the European Union (EU) have led to an increase in Malta’s pharmaceutical activities.¹

REFERENCES

³ Brocklebank, M.P., et.al., A hub layout concept for oral solid dosage (OSD) facilities, Pharm. Eng. 26, 1.