

Recent Publications

Small-scale manufacture of pharmaceutical preparations in developing countries

Many countries have no indigenous pharmaceutical industry and are almost exclusively dependent upon imported pharmaceutical products. In such countries, reliance is often vested in hospital dispensaries to formulate products that would otherwise be unobtainable. Foremost among these are large-volume parenteral fluids, both because the cost of transporting them is high and because a variety of formulations needs to be immediately available in virtually every referral facility.

Safe and reliable production methods must be devised, often on a severely restricted budget, but in all circumstances a good quality product must be assured. Fortunately, it is often possible to meet rigorous safety requirements simply by scaling down production processes. The International Pharmaceutical Federation has performed a valuable service by producing a set of practical guidelines that will assist many supervisors working in hospital dispensaries in developing countries to meet exacting standards in preparing large-volume parenteral fluids.

The guidelines are based on the premise that batch size will be restricted to a maximum of some 100 litres — a volume that can be loaded into small-scale stills and sterilizers. They also require the operations to be supervised by persons fully aware of how quality can be endangered, who are prepared to work to validated, written Standard Operating Procedures, and Plant Operating Procedures and who will maintain high standards of documentation. Importance is also placed upon the need for all personnel to appreciate the importance of their own contribution to the production of safe and efficacious products. The use of self-auditing procedures are recommended as instilling a sense of pride in personal achievement.

Sterilization, it is emphasized, is one of the most critical activities in the preparation of intravenous fluids. Relatively inexpensive manually-operated autoclaves have few complex parts to go wrong, but the responsibility for successful sterilization falls

more heavily on the operator, and the outcome is dependent upon the attitudes and skills that are applied to the task.

In essence, the guidelines extrapolate and interpret the principles of Good Manufacturing Practice to an environment in which, because of its simplicity, they need to be heeded with particular rigour.

Surprisingly, however, the guidelines are silent on the training and qualifications that should be reasonably expected of a manager of such a production facility. The knowledge, skills and attitudes required are those that are inculcated in the study of pharmacy. Regrettably, however, pharmacy remains a conspicuously under-represented profession in many developing countries. Nor, until now, has the profession received much by way of formal recognition within WHO or its governing bodies.

Belatedly, this oversight is now corrected. The Forty-seventh World Health Assembly, at its meeting in May this year, has been invited to adopt a resolution that depicts the technical and administrative capabilities of the pharmacist, and that acknowledges the contribution the profession can offer at every level in the health care infrastructure. Member states will be encouraged to assess their needs for pharmaceutical services, and for relevant training facilities.

This is a timely acknowledgement, given the increasing attention that both the International Pharmaceutical Federation and the Commonwealth Pharmaceutical Association have accorded to the problems and needs of the developing world over the past decade. Meaningful support to the profession in these countries must have immediate practical application. Technical guidelines, such as those concerned with the production of large-volume parenteral products, will do much to set pharmacy on a secure footing where it is currently most acutely needed.

Guidelines for small-scale hospital production of large volume parenteral fluids in developing countries. The Netherlands. Section of Hospital Pharmacists, International Pharmaceutical Federation, 1993.