Combination Products: Drugs and Devices

1 INTRODUCTION

Recent years have seen a vast increase in the number of new therapeutic products which are not purely drug, device, or biological, but rather a combination of two or more of these. Classical examples are implanted drug delivery systems (whose primary function is drug delivery) and drug-impregnated devices (in which drug delivery is an adjunct to the device function). Congress first acknowledged the need for specific regulation of such combination products in the 1990 Safe Medical Device Act.

2 HISTORICAL BACKGROUND

The history of this category includes a variety of product types dating at least from the perfection of the hypodermic needle (1855). There are many modern examples of implanted delivery systems, such as the insulin pump (1980). One fundamental driving force for delivery systems has been the growth of new pharmaceutical products, especially since the dramatic expansion of drug research after 1945.

That research has led to the synthesis and testing of millions of compounds for pharmacological and antimicrobial properties. Indeed, today much of that development is performed in automated computer-controlled systems, leading

Pharmaceutical Sciences Encyclopedia: Drug Discovery, Development, and Manufacturing
Edited by Shayne C. Gad