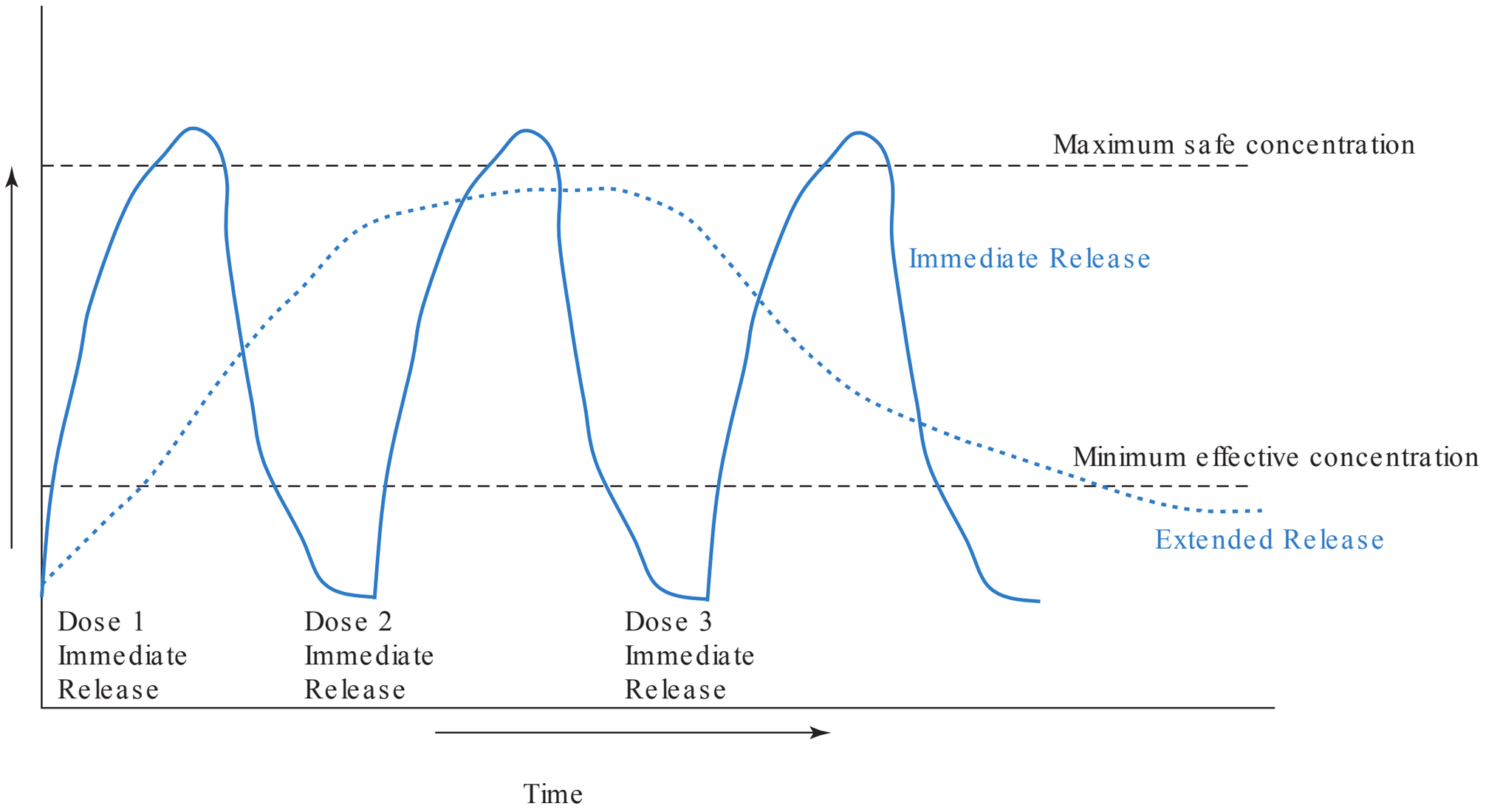

Fig. 31.3 • Figure showing theoretical plasma (blood) profles of immediate and extended release. The immediate release dosage form requires three doses to keep the drug levels effective over the time period shown and the maximum concentration (C_{max}) exceeds the upper safety limit in this example. The extended release profle (dotted line) represents one dose of a sustained release dosage form over the same time period. The latter reduces C_{max} and extends the release.

What modifed-release drug delivery means for the healthcare professional and pharmaceutical industry

Provides doctor, pharmacist and patient choice. Healthcare professionals will be primarily concerned with the therapeutic advantages outlined above, but increasingly there is concern for personalized medicines and health services. A choice of immediate-release dosage forms and modifed-release dosage forms can allow healthcare professionals to tailor treatment to their patients' needs.

Product life extension. Improving on current marketed formulations by employing modifed-release technologies can sometimes enable pharmaceutical companies to extend a product's patent life.

Higher development costs. There are much higher costs for pharmaceutical companies in developing a modifed-release formulation compared to a conventional immediate-release dosage form.

Cost savings to healthcare providers. Cost-savings may be achieved from better disease management.

Sites of action for modifed-release dosage forms and biopharmaceutical considerations

The gastrointestinal tract

Biopharmaceutical factors (i.e. the effect of the gastrointestinal physiology and environment on drugs and dosages forms) are considered in more detail in Chapter 19. Here some of the key biological factors that influence the *in vivo* behaviour of modifed-release dosage forms are summarized and discussed. To understand these, the factors limiting drug bioavailability should be noted. The overall process of drug release and absorption will only be as fast as the slowest of many processes. The most common possible rate-limiting steps following oral administration of a solid dosage form are (1) drug release from the dosage form, (2) dissolution of the drug or (3) absorption of drug molecules.

pH

The stomach generally has a low pH and is therefore acidic. Gastro-resistant coated dosage forms