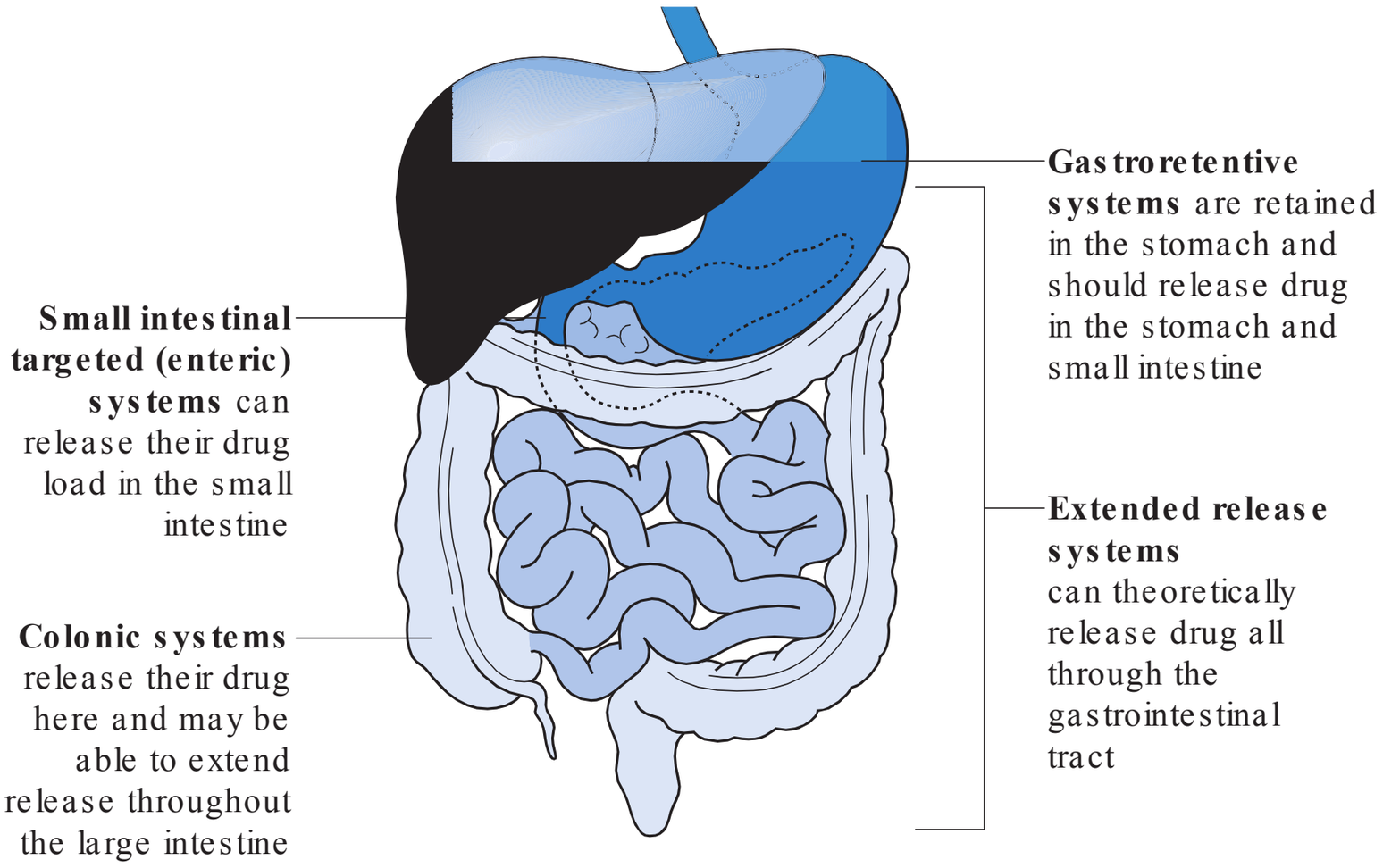

Fig. 31.1 • The site of action for various oral modifed drug delivery systems.

dosage form (e.g. tablet, pellet, capsule) with the specific aim of delivering active pharmaceutical ingredients (API) at:

1. desired rates

2. pre-defined time points, or

3. specific sites in the gastrointestinal tract.

Modified-release drug delivery is a broad term which covers a variety of different approaches. These will be dealt with in further detail throughout this chapter. Briefly, the different types are:

- Delayed-release dosage forms: these release drug at a time later than immediately after administration (i.e. there is a lag time between a patient taking a medicine, and drug being detected in the blood). *Site-specific targeting* is a type of delayed release which aims to target specific regions of the gastrointestinal tract, e.g. the small intestine or colon.
- Gastro-resistant dosage forms: these are designed to have a type of delayed release mechanism which enables that the drug is released when a certain environmental pH is met. A common example of this type of dosage form ensures that the drug is not released in the acid of the stomach but in the higher pH of the small intestine. Such products may also be known as enteric dosage forms.
- Extended-release dosage forms: these allow a reduction in dosing frequency compared to when the drug is present in an immediate-release dosage form (i.e. the drug plasma levels are sustained for longer periods). These are also known as *prolonged-release* or *sustained-release* dosage forms and are also referred to as *controlled-release* dosage forms. Extended-release systems which are retained in the stomach are known as *gastroretentive systems*.

The site of action of each of these systems is shown in Figure 31.1.

The concept of modified-release dosage forms has been around since the late 1800s when the idea of protecting the stomach from irritant drugs triggered a search for gastro-resistant materials. As knowledge of the gastrointestinal tract increased (pH, bacteria, transit times), the success and scope of the dosage forms targeted to the gastrointestinal tract improved. In recent years, there has been a huge increase in the number of patents filed for modified-release dosage forms (Fig. 31.2) highlighting the intense interest of the pharmaceutical industry in exploiting the benefits of these technologies to improve product performance.

What modified-release drug delivery means for the patient

Keeping drug in the therapeutic range. Modified release is often used to improve therapeutic