



Figure 1.1 Analytics and process metrics. LMW: Low-molecular weight. (From <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeForPharmaceuticalScienceandClinicalPharmacology/UCM315764.pdf>.)

a part of a microbe that is essential for its invasion and survival). The ability of an antibody to communicate with the other components of the immune system is mediated via its fragment crystallizable (Fc) region (located at the base of the Y), which contains a conserved glycosylation site involved in these interactions. The production of antibodies is the main function of the humoral immune system.

Although the general structure of all antibodies is very similar, a small region at the tip of the protein is extremely variable, allowing millions of antibodies with slightly different tip structures, or antigen-binding sites, to exist. This region is known as the hypervariable region. Each of these variants can bind to a different antigen. This enormous diversity of antibody paratopes on the antigen-binding fragments allows the immune system to recognize an equally wide variety of antigens.

Hormones are a class of signaling molecules produced by glands in multicellular organisms that are transported by the circulatory system to target distant organs to regulate physiology and behavior. Hormones have diverse chemical structures including eicosanoids, steroids, amino acid derivatives, peptides, and proteins. The glands that secrete hormones include the endocrine signaling system. The term *hormone* is sometimes extended to include chemicals produced by cells that affect the same cell (autocrine or intracrine signaling) or nearby cells (paracrine signaling).

The protein hormones are synthesized in cells from amino acids according to messenger ribonucleic acid (mRNA) transcripts, which are synthesized