from previous use of the candidate compound in humans is described in this section. Human data may be available from studies performed in other jurisdictions or from previous attempts to gain marketing approval in different disease state.

The second section provides detailed information on Chemistry, Manufacturing, and Controls (CMC). A detailed description of the manufacturing methods including synthetic methods for producing the API, as well as information on all of the excipients and how the clinical formulation will be prepared must be included. It must also include information on impurities that are produced as part of the process, methods for assessing purity of each batch that is prepared, and evidence that equivalent drug batches can be produced in a reliable and consistent manner. Of course, in order to have this information, manufacturing capacity must already be in place and sufficiently tested to demonstrate its capacity to produce the drug product.

The third and final section covers the clinical protocols and the individuals involved. Clinical studies must be described in sufficient detail such that the regulatory agencies can assess whether or not the program will expose the subject to unnecessary risks. In addition, information on the study centers (most clinical trials employ multiple study centers) and the qualifications of the people running the programs and overseeing administration of the clinical candidate (most often physicians) is provided as evidence that the facilities and personnel are sufficient to ensure the safety of the study participants. Adherence to regulatory guidelines, methods of obtaining informed consent of all study participants, and the establishment of an Institutional Review Board (IRB) are also described in this section of the document. An IRB, also referred to as an independent ethics committee or ethical review board, is a committee that is tasked with ensuring that clinical trials are run in an appropriate manner. They are formally charged with the tasks of monitoring, reviewing, and approving all aspects of the clinical programs. This includes any changes to protocols that may be required as a result of new data that emerges through the course of the trials. Risk to benefit analysis may also be performed by the IRB as the clinical trials move forward in order to determine whether or not it is safe to continue the trials.

It should come as no surprise that INDs are exceptionally large documents that require a significant amount of effort to prepare. They are generally written by a large team of sufficiently qualified individuals. Typically, the investigators will meet with representative of the appropriate regulatory body (e.g., FDA, EMA, etc.) in order to ensure that the clinical program design will be sufficient. At the end of the day, all clinical programs must be approved by the regulatory agencies before they can be