This part of the CFR also defines a serious adverse drug experience, as follows (47):

> *Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.*

The investigator and medical writer may want to review the *Federal Register* from time to time to learn of proposed definitions relating to drug safety and efficacy. In the *Federal Register*, when there is an actual change in the law, it is called a "Final Rule."

1. Adverse events

The FDA's Guidance for Industry provides the following definition of adverse events (AEs) (48):

> *An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.*

2. Serious adverse event

The FDA's Guidance for Industry provides the following definition of serious adverse events (SAEs) (49):

> *Any untoward medical occurrence that at any dose:*

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.

[47] 21 CFR 310.305(b) (April 1, 2010 version).

[48] U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for Industry. E6 Good clinical practice: consolidated guidance (April 1996).

[49] U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for Industry. E6 Good clinical practice: consolidated guidance (April 1996).