

BSE-Prion

Hideharu Shintani*

Faculty of Science and Engineering, Chuo University, 1-13-27, Kasuga, Bunkyo, 112-8551, Tokyo, Japan

Adventitious agents are those that are not inherent in the production of biopharmaceuticals. Microbial adventitious agents include viruses, bacteria, fungi, and mycoplasma. Transmissible spongiform encephalopathy (TSE) agents are also potential adventitious agents. Raw materials may contain adventitious agents. Adventitious agents can be introduced during establishment of cell lines, cell culture/fermentation, capture and downstream processing steps, formulation/filling, and even during drug delivery. Therapeutic biotechnology products have an excellent safety record. However, the potential introduction of adventitious agents must continually be evaluated. The testing that is performed for this purpose is addressed in regulatory documents that include ICH guidelines, US. Points to Consider, and European, U.S., and Japanese Pharmacopoeia (EP, USP and JP) documents. In some cases, 9 CFR (U.S. Code of Federal Regulations) and 21 CFR, 211 and 610 are applicable.

Since biopharmaceuticals encompass many types of products, there is considerable variability in risks from adventitious agents. In all cases, however, the use of Good Manufacturing Practices (GMPs) (e.g., environmental controls, control of raw materials and personnel flow, and cleaning), suitable safety testing programs, and process validation

(including viral and sometimes mycoplasma clearance evaluation) helps to ensure patient confidence in biopharmaceuticals. Some products have minimal inherent risk associated with the introduction of adventitious agents (e.g., recombinant products produced in bacteria). Other types of products, such as those used for cell or gene therapy, are often at the other end of the spectrum and may be associated with greater risk due to their inability to tolerate rigorous processing conditions. Greater potential risks are often associated with the use of human cells and animal-derived raw materials. Of particular concern are materials derived from bovine and porcine sources. When viable cells are a component of the product (as in *ex vivo* transduction), there may not be sufficient time to perform the required safety testing. In such cases, product may be released prior to completion of relevant tests for adventitious agents, although this testing is still mandated in order to demonstrate that the processes are being performed under adequate controls to maintain patient safety. A risk/benefit analysis determines whether the use of these products is warranted. We need to prevent and control of risks arising from various stages of production. We must confirm that several risks are associated with various sources and must not overlook the risks associated with several sources.

***Corresponding author:** Hideharu Shintani, Faculty of Science and Engineering, Chuo University, 1-13-27, Kasuga, Bunkyo, 112-8551, Tokyo, Japan, Tel: +81425922336, Fax: +81425922336; E-mail: shintani@mail.hinocatv.ne.jp

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