A Structured Approach for Auditing the Microbiology Laboratory

By **Tim Sandle**

Jan 23, 2019 2:07 pm EST

Introduction

Producing consistent and reliable data is the function of any laboratory; this is necessary in order to make decisions about the quality of the finished product. Microbiology laboratories supporting pharmaceutical and healthcare facilities will, under the quality system, be subject to periodic audit. While many aspects of the audit will be similar to any standardized approach to auditing a general laboratory (as an earlier article sets out), there will be specific areas that require examination for which some understanding of the role of the microbiologist will be required by the auditor. This article addresses many of these microbiological-specific issues.

The audit should be seen as far more than a walk around a laboratory, with asking of a few questions to whomever is in the vicinity. The audit process requires adequate planning, time management during the audit itself, a clear focus on the purpose of the audit. The audit should be clear how the level of compliance will be assessed and on what basis the audit will be regarded as successful or otherwise.

Such issues will include, as USP <1117> points out: aseptic technique, control of media, control of test strains, control of equipment, diligent recording and evaluation of data, and appropriate training (1). In addition, the audit may extend to issues of biosafety, waste management and the good optimization of space (where poor design can lead to sample mix-ups or pose contamination risks to laboratory staff and to visitors).