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Microbiological control symposium: consensus on readiness of new methods emerges

A symposium on microbiology in the pharmaceutical sector was the opportunity for the EDQM to gather feedback from users of the European Pharmacopoeia on alternative testing methods for microbiological control and sterilisation processes. The event, which took place in Strasbourg on 10-11 October 2017, was attended by a wide range of experts in the pharmaceutical and microbiological fields who reviewed the latest trends and innovations in the field of microbiology, in addition to Pharmacopoeial approaches and related regulatory requirements.

During the symposium, a consensus emerged among participants that alternative methods for the detection, enumeration and identification of microorganisms are at present sufficiently well covered in Pharmacopoeias world-wide. General agreement was also reached that developments in Pharmacopoeias now allow manufacturers of medicines to start using modern technologies for effective microbiological control.

Among the topics covered was the use of modern methods for microbiological control, with specific sessions focusing on sterilisation and biological indicators, rapid microbiological methods and control methods for cell therapy products and pharmaceutical water. Reports on successful new methods gave an overview of the potential benefits in terms of costs and time efficiency and, most importantly, in terms of quality. Authorities, manufacturers and suppliers of new technologies also discussed the current acceptance of these new methods at a regulatory level across the world.

Over recent years, the European Pharmacopoeia has given pharmaceutical manufacturers access to new chapters for microbiological control, kick-starting a new era for the world of microbiology and rendering the uptake of modern microbiological methods an evolution already in process, rather than a revolution.

Various chapters of the European Pharmacopoeia have laid the foundations for the use of modern methods for microbiological control and have been available for more than ten years – notably *5.1.6. Alternative methods for control of microbiological quality*, *2.6.7. Mycoplasmas*, *2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests* and *2.6.27. Microbiological examination of cell-based preparations*. Chapter *5.1.6* in particular was recently further revised to take into full account the latest technological developments and to provide clear guidance for validating alternative microbiological methods.

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Note for the Editor: Further information is available on the internet site **www.edqm.eu**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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