



NEWS



EDQM “RTEMIS” pilot project: real-time remote GMP inspections of API manufacturers

Interruptions to the inspection programme of the European Directorate for the Quality of Medicines & HealthCare (EDQM) due to travel restrictions – made necessary by the COVID-19 pandemic – led to the creation of a system of Real-Time Remote Inspections (RTEMIS). This pilot project combines a live video feed, linking inspectors and manufacturing sites of active pharmaceutical ingredients (APIs), and the review of documentary sources, with the objective of monitoring compliance with both Good Manufacturing Practice (GMP) and applications for Certificates of suitability to the monographs of the European Pharmacopoeia (CEPs) in manufacturing sites.

The EDQM inspection programme is an integral part of the CEP procedure and is therefore essential to ensuring the availability of good quality medicines. Because the vast majority of inspections takes place in India and China, the EDQM had to find new ways to continue the GMP evaluation of manufacturing sites, complementing the traditional combination of on-site inspections and documentation-based assessment of companies.

Technical and administrative solutions meeting strict requirements in terms of information confidentiality and security, inspector safety and of course the effectiveness of the site inspection procedure itself were first examined in detail during a feasibility study, then put into practice in a pilot phase with several manufacturing sites in India.

These sites, selected on the basis of their GMP-compliance history and a risk assessment, were invited to participate on a voluntary basis.

The objectives of these initial inspections were achieved: a number of minor and major deficiencies were observed and the Corrective and Preventative Action Plans the companies put in place led to a satisfactory degree in GMP conformity on the remotely inspected sites.

Circumstances and safeguards appropriate for real-time remote inspections are being further examined, but the EDQM considers that real-time remote inspections could be fully integrated into its inspection programme in the future. While this approach cannot replace on-site inspections in terms of value and effectiveness, it does enable inspectors to assess GMP-compliance for companies already having been inspected by the EDQM. Real-time remote inspections could therefore become a third pillar for the supervision of GMP compliance of API manufacturers registered in the EDQM's CEP scheme.

For more information, see the EDQM's dedicated web page: [“EDQM and real-time remote GMP inspections of API manufacturers during the COVID-19 pandemic: innovation overcoming adversity”](https://www.edqm.eu/en/news/edqm-rtemis-pilot-project-real-time-remote-gmp-inspections-api-manufacturers)

Reference:

<https://www.edqm.eu/en/news/edqm-rtemis-pilot-project-real-time-remote-gmp-inspections-api-manufacturers>