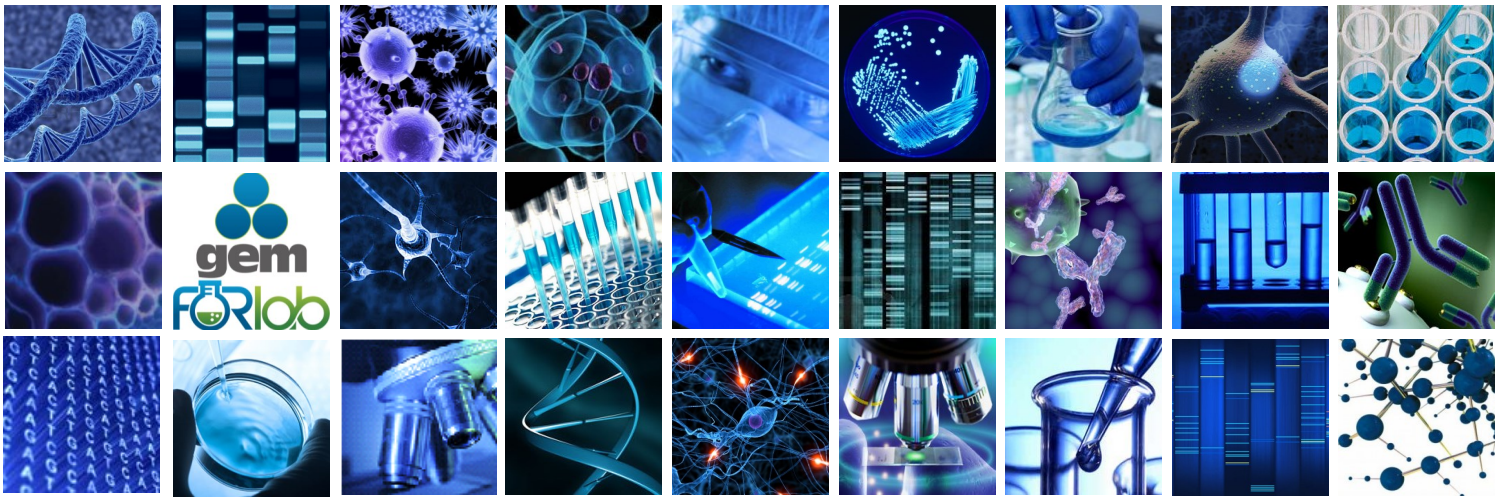

Detection of viral contamination by Real Time PCR as quality control

Aim of the study

Detection and quantification of a variety of viral nucleic acids, in order to spot the presence of possible contaminations in production batches, as quality control.

Analyte

RNA and DNA from 13 different viruses

Methodology

Real Time PCR offers a highly sensitive quantitative method for determining contaminating nucleic acids in production batches of biological drugs. Absolute standard curves were used to calculate copy number of viruses.

System Production batches

Therapeutic area Quality Control

Development stage Manufacturing

Customer A multinational pharmaceutical company commercializing biological drugs

Results

Support for the client was given to develop quality control assays for assessment of contamination in production batches of 13 different viruses.
Part of the assays were designed by the client and optimized at our laboratories, while other viral nucleic acids were sequenced and dedicated qPCR assays were designed using fluorescent hydrolysis probes technology. LOQ was defined on synthetic DNA spiked in genomic DNA matrix. Optimization of the assays included specificity tests, optimization of primer and probe concentration, amplification efficiency and linearity.

Advantage of the methodology

Contamination of viruses in production batches is traditionally tested by performing infectivity assays. Although Real Time PCR gives no information about infectivity, it is a fast and quantitative method that can be used to assess contamination by viral RNA or DNA.

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