Detection of Cow & Pig DNA in Heparin

Customized Multiplex qPCR Assay Development
High-Throughput Testing Including Heparin Digest

Project Challenge
Heparin is widely used as an injectable anticoagulant and as anticoagulant coating on various experimental and medical devices. Pharmaceutical grade heparin is derived from mucosal tissues of pig intestines or bovine lungs. Microsynth was inquired by an industrial customer to develop a sensitive multiplex real-time PCR assay, which is suitable to quantify residual traces of pig and cow DNA in heparin and conduct routine testing on heparin samples. Since heparin is known to be a strong inhibitor in PCR/real-time PCR assays, a major challenge of the project was to develop a robust protocol, which includes the specific digestion protocol of heparin.

Project Realization
In a first phase, a protocol for specific digestion of heparin was initially established and validated. Then, a thorough qPCR assay strategy was defined, which on the one hand allows to detect porcine & bovine traces of DNA in heparin samples and on the other hand allows to assess the quality/completeness of the heparin digest. A triplex qPCR assay approach was selected which simultaneously detects a cow-specific, a pig-specific as well as an internal control marker. The control marker is used in combination with an artificial template and is added to each heparin sample. Hereby, it is possible to verify the effectiveness of the heparin digest in each sample and rule out any false-negative results. In a second phase, heparin samples were analyzed using SOPs that had been established during the initial set-up and validation phase. Finally, the data was analyzed and reported to the customer.

Customer Benefit

- Microsynth defines and realizes a thorough qPCR strategy for cost-effective detection of porcine and bovine traces in heparin samples.
- All from one single source: DNA isolation, multiplex qPCR assay development, production and validation as well as routine testing.
- Microsynth completed the project in time and in accordance to the budget guidelines.