HCL Expedites Biocompatibility Failure Investigation

Multinational medical device company meets regulatory requirements with HCL's approach

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About the Client

The customer is a US-based multinational medical devices company. This customer recently expanded its product portfolio to include hi-tech healthcare products for vital sign monitoring, imaging, medical, and life sciences instrumentation.

Business Objectives

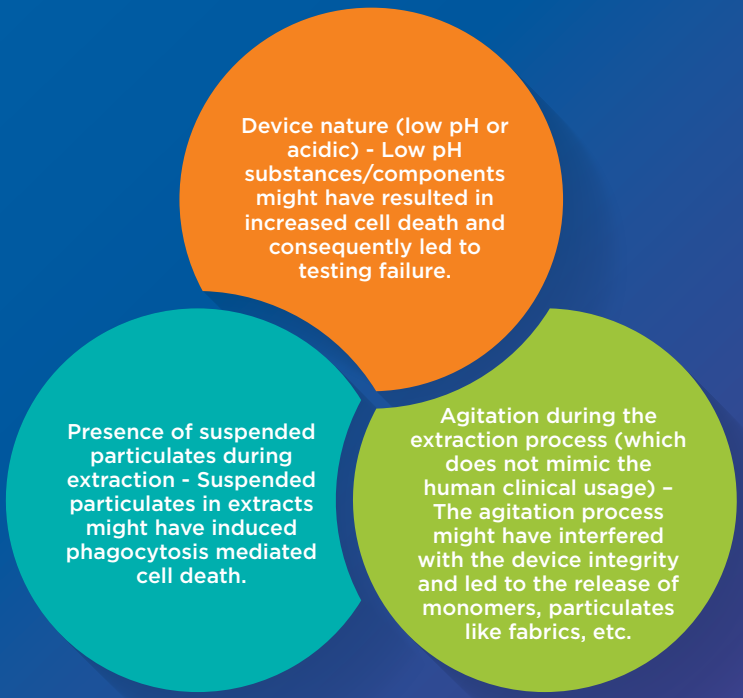
Its newly developed wearable device for Cardio-Pulmonary vital measurement failed the biocompatibility test as one of its components, hydrogel, failed the cytotoxicity test. The customer had to delay its submission to the regulator. This stalled the customer's plans of a product launch too.

The customer chose HCL to help fix the cytotoxicity test issue with the said product in a month although the industrial benchmark for investigating similar critical failure is two months. The customer and HCL were focused on one thing: ensuring patient safety to launch the medical device.

HCL's Solution

HCL performed a detailed failure investigation considering all the previous procedure-related parameters (test article, device preparation, and testing conditions). Our expert team framed a comprehensive experimental design by considering the clinical use condition. This was done to avoid procedure-related failure and meet the regulatory guideline requirements.

HCL analyzed the possible reasons for device failure based on previous study results and identified three evident reasons:



To address the identified test failure factors, HCL followed a unique testing strategy, which includes:

1. Adjusting the extract pH between 7.2 to 7.4 to make the extract compatible with the test system.
2. Filtering the device extracts to remove suspended particulates.
3. Maintaining a static extraction condition to avoid the release of monomers and other particulate matters.

Other possible failure factors such as sterilization, duration of extraction, and test item components/combinations were also considered to create a robust experimental design.

HCL tested the medical devices in a state-of-the-art Contract Research Organization (CRO) facility and provided world-class test support – support that is highly dependable and acceptable among global medical device regulators (US FDA, EU notified bodies, etc.). HCL successfully delivered the proposed failure investigation with zero delays.

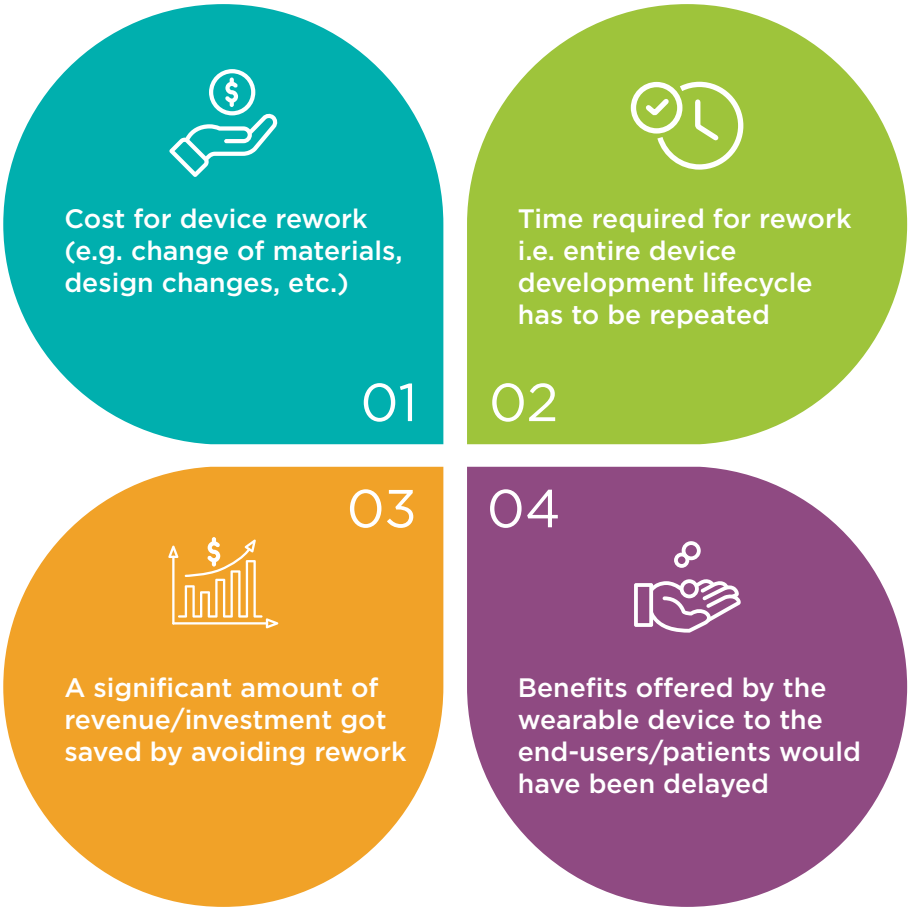
- Timely execution of the biocompatibility test (within a month)
- Failure investigation performed and reason for failure reported
- Consultation support from qualified and certified professionals
- Internationally acceptable investigation and reporting (rationale/justification)

Biocompatibility test data with the below observations finally concluded that the wearable device in its clinical use condition is safe for intended application meeting all the requirements.

01	02	03	04	05
Sterilization does not influence the cytotoxicity reaction	Extraction duration does not influence the cytotoxicity reaction	Static extraction condition (which mimics the clinical usage) has lesser/no influence on the cytotoxicity reaction	Filtration of extract influences the cytotoxicity reaction	pH adjustment has a major influence on the cytotoxicity reaction

Benefits Delivered

Failure investigation proved that the test item failed due to test procedure-related parameters, and not by the device itself. This avoided a huge business impact for the customer in terms of:



The customer was able to submit its reports to the regulatory authorities on time. This medical device is expected to hit the market in the last quarter of 2021 without any further delay.