

Calibration Systems Integrity at Overseas Contract Manufacturer Facilities

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Abstract

As manufacturers steadily increase the number of production lines that are sent to contract manufacturers (CMs) outside of the United States, concerns about maintaining product quality is often one of the first subjects to be brought up and one of the last to be placed in the “closed action item” file. Although a contractual document may be in place, it provides little comfort when the reality of the situation is that things are falling apart and your customers are asking for immediate correction action – yesterday.

Everyone knows that instrument calibration is considered to be a necessary evil by many in North America and the EU. In less regulated communities, where production and cost elimination are paramount concerns, calibration programs may be little more than an electronic (formerly rubber) stamp on an electronic (formerly paper) certificate of conformance.

This paper is intended to discuss some of the real world challenges that US companies have faced as they’ve expanded into primarily Asia-Pac areas and some of the ways that they have sought to mitigate actual concerns and perceived issues.