



ISO 13485 : 2016

Quality management  
for medical devices

# CTK

# INSIGHTS

Volume 1, Issue 1, 2017

## Keeping a Competitive Edge in IVD

All businesses that operate in competitive markets feel pressure from their customers and their competitors to reduce prices while still maintaining maximum product quality and performance. The balance of achieving this has been a challenge for CTK Biotech especially while we try to keep an eye on the company's mission to improve global health by providing simplified diagnostics.

Jeff Russell, Global Medical Device Practice Director at Camstar, shared these top five challenges facing medical device manufacturers in an interview with Siemens:

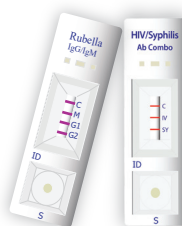
1. Reduce costs to offset margin pressures
2. Reduce the costs and risks of compliance
3. Ensure supply chain stability
4. Speed up and stabilize new product introduction (NPI)
5. Manage top line revenue impact

At CTK Biotech, we work diligently to manage costs, stability, and development speed to ensure that our products are affordable, dependable, and up-to-date for health care providers and patients in local markets.

We would like to share with you some of the steps that has CTK taken to keep costs down and quality up.

### Cost effective product design

- Develop multi-line tests to give multiple test results from a single device with a single procedure:
  - A 4-line Rubella semi-quantitative rapid test
  - A 4-line HIV 1/2/0 rapid test
  - A 3-line Hepatitis rapid test (HCV/HBV)
  - A 3-line test for HIV and Syphilis



### Cost efficient production

- Increased automation in manufacturing from the beginning to packaging, such as:
  - Automated laser printing on cassettes to increase versatility and customization options
  - Automated strip assembling and pouching system
  - Constant capture QC reader for rapid tests
- Transition to new ISO 13485:2016, WHO pre-qualification, and 5S manufacturing process to bolster operation systems, increase productivity, and minimize non-confirming products
- Product made from key reagents made in house

### New product development

- Adding more product lines to offer a complete diagnostic solution from screening to confirmation including high throughput
- Develop products that can be used in remote areas, physician offices, small laboratories, and busy labs or big hospitals

These improvements are just a few of the ways that we are working to keep a competitive edge in the IVD industry for both CTK and our loyal distribution partners!

## ASK THE EXPERT

Introducing Ask the Expert, a new section to be featured in our upcoming newsletters dedicated specifically to providing answers and explanations to some of your most common questions.

Submit your questions on our website (<http://ctkbiotech.com/contact/>) or message us on Facebook using the tagline "Ask the Expert" and you'll automatically be entered in for our end of year drawing!

Be on the lookout to see if your question gets featured in our next newsletter!

## MEET US

- Hospitalar, Brazil, May 2017
- AACC, USA, July 2017
- Medica, Germany, Nov 2017

CTK-MK-NLR-V1112017 Rev1.0

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