

# An integrated quality system for high-quality contract manufacturing



## About The Dot

The Dot is a contract manufacturing firm that manages test kit assembly, relabeling, fulfillment, logistics and distribution for clients.

The company began working closely with medical device manufacturers and healthcare businesses in 2010, but saw a huge spike in interest in the aftermath of COVID-19.

## The challenge

As COVID-19 began shutting down the world, The Dot experienced an increase in business.

Several key healthcare and medical device clients began enlisting the company’s services to help secure their supply chains and ensure they could continue bringing life-saving products to market.

Quality Assurance Specialist Edgar Gimenez’ focus was continual improvement and building cGMP-compliant processes — but The Dot’s old system required him to spend too much time on document management, and not enough time on value-add system improvement.

To give new clients peace of mind and to embed cGMP at unprecedented scale, The Dot needed a transparent, integrated quality management system that would give customers visibility into their manufacturing processes and earn their trust — while freeing up admin time for more productive quality work.

*“Qualio helped us achieve a high level of deployment in a short amount of time. It’s very visual, very easy to understand, and very intuitive.”*

— Edgar Gimenez  
Quality Assurance Specialist, The Dot

Industry	Contract manufacturing
Regulations	<ul style="list-style-type: none"><li>• FDA 21 CFR 210/211</li><li>• cGMP</li></ul>
Uses Qualio for	<ul style="list-style-type: none"><li>• Documents</li><li>• Training</li><li>• Events</li></ul>

1

System for robust cGMP

100%

Quality support with Qualio+

100%

Elimination of document admin



# The solution

The Dot began looking for a quality management system that was easy to use, reliable, and could scale to meet the needs of their operation.

After doing their due diligence, the team ultimately decided that Qualio was most able to meet their needs.

The Dot also invested in Qualio+, which gave Edgar access to expert QA support from the Qualio team alongside the software itself.

*“Qualio shows we're taking quality seriously and investing in quality improvement initiatives.*

*We plan to keep growing with Qualio, offering visibility, continuous improvement and knowledge management to our current and potential customers.”*

— Edgar Gimenez

Quality Assurance Specialist, The Dot

## The results

### Edgar and the team unlocked an efficient, cloud-based cGMP platform that met every need



#### Clear information management

The Dot needed a formalized system to document processes and procedures, and assign responsibilities for achieving quality policies and cGMP objectives.

Qualio gave The Dot a **holistic document management system** for recording processes and managing the organization's knowledge from one place. Edgar notes that:

*“We can track our processes now and achieve the consistency we need, which brings value to our organization. I don't have to worry about versions; everything is done automatically.”*



#### Rapid set-up with Qualio+ support

The Dot was able to get their shiny new eQMS up and running quickly thanks to the impressive onboarding support the Qualio team delivered.

And Qualio+ took things a step further, offering both **cGMP guidance** and **pre-built document templates** to strengthen The Dot's compliance and quality. Edgar believes that:

*“I think Qualio+ has been the most valuable thing. It's allowed me to deploy an eQMS across an organization in a record amount of time. They were there 100% of the time, offering solutions for the success of our initiative here.”*



#### Scalable cGMP platform

Qualio gave The Dot the insight and visibility to **continuously improve** their manufacturing processes and embed **robust cGMP**.

The previous time commitments of manual document admin and on-premise system upkeep have been eliminated, **freeing up Edgar's time** for thoughtful, proactive, value-add quality planning that attracts fresh business and raises the industry profile of The Dot.

Due to Qualio's **cloud-based** nature, The Dot doesn't have to invest precious IT resources into eQMS upkeep and can let Qualio take care of their system maintenance.



#### Ready for the future

As The Dot makes further inroads into the healthcare and medical device industries for fulfillment and assembly, the team is confident they have an eQMS that can support their mission at scale and help them **pass customer and regulatory GxP audits with ease**.