

QUALITY'S IMPACT ON THE GLOBAL PANDEMIC RESPONSE



INTRODUCTION

The COVID-19 pandemic continues to impact every aspect of life worldwide. People are only beginning to understand the long-term health, economic, sociological, and psychological effects of these historic times. Put simply, the pandemic has presented the greatest challenge of the 21st century to date. Challenges, however, present opportunities for humanity to innovate and collaborate to continue to achieve their goals. ASQ was established out of one of the greatest challenges of the 20th century, World War II. This global war required an industrial and manufacturing revolution for victory. The resulting manufacturing expansion continued at a historic pace for the following three decades. ASQ was established to ensure that the companies and professionals leading this expansion developed and proliferated best practices to ensure optimum product quality and efficiency as the economy grew.



2021 is ASQ's 75th anniversary year, and the Society has advanced its mission of empowering the individuals and communities of the world to achieve excellence through quality across dozens of diverse industries—many of which are directly responsive to the pandemic mitigation effort. Over the course of the next three months, the Society will explore the role of quality in every aspect of the COVID-19 response. From immunization development and approval, to supply chain delivery, to actual administration of the immunization in a healthcare setting—quality initiatives have been integral to the historic response effort. Highlighted below are each of the key response stages, and how quality best practices have informed those processes. ASQ members and ASQE Organizational members have always shared the goal of solving problems that improve and advance our lives and communities. These efforts are helping to ensure that the immunization process is as safe as modern science and quality innovations can guarantee.

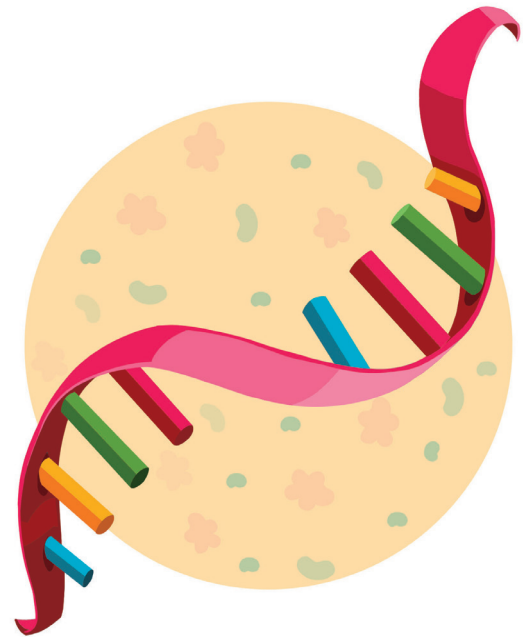
ENSURING SAFE VACCINE DEVELOPMENT AND APPROVAL

Foundational quality principles guide both the private sector development and expedited Food and Drug Administration (FDA) approval of the COVID-19 vaccine. The first COVID-19 vaccines authorized were messenger RNA vaccines or mRNA vaccines. Though research into mRNA vaccines has occurred for years, the COVID-19 vaccines are the first to be clinically approved by the FDA.¹ The typical vaccine development and approval processes take 12 years. The COVID-19 virus was only discovered in human populations 18 months ago. So, how did both industry and the FDA respond so quickly? Quality fundamentals and resource allocation were the key factors in accelerating the timeline.



For pharmaceutical organizations creating vaccines, quality is built into the core processes of their organizations, allowing them to accelerate in times of need. Stephanie Gaulding, Director of Regulatory Compliance at Pharmatech Associates, sees Joseph Juran's Quality by Design (QbD) framework as continually influential throughout the pharmaceutical industry.

"When we design new products and processes, thinking about quality in the product and process is done from the very start... the reason that these vaccines moved so fast is that these companies had the quality foundations necessary to do rapid development, scale-up, and ultimately get data in front of the FDA quickly."



Which ASQ technical community members are involved in vaccine development and safety? Key contributors include:

- Chemical Process and Industries
- Food/Drug/Cosmetic
- Government
- Healthcare
- Human Development and Leadership
- Innovation
- Medical Device
- Quality Management

With public need and scrutiny at an all-time high, organizations developing the vaccine created risk assessments before, during, and after the development and manufacturing of the vaccine. Assessments like Failure Modes & Effects Analyses were completed early in the development phase, allowing organizations to address potential errors and defects.

The FDA has also released its own set of quality recommendations for the COVID-19 vaccine, including implementing a quality control system for all stages of manufacturing.² To get approval from the FDA, organizations had to pass approval for both the Emergency Use Authorization (EUA) and Business Licensing Agreement requirements. The organizations that were successful under the EUA were those who had embedded quality principles, like Lean thinking, and the quality infrastructure established before the COVID-19 pandemic. Jeremiah Genest, Senior Director of Quality at Vertex Pharmaceuticals, summarizes the FDA's long-standing connection to quality:



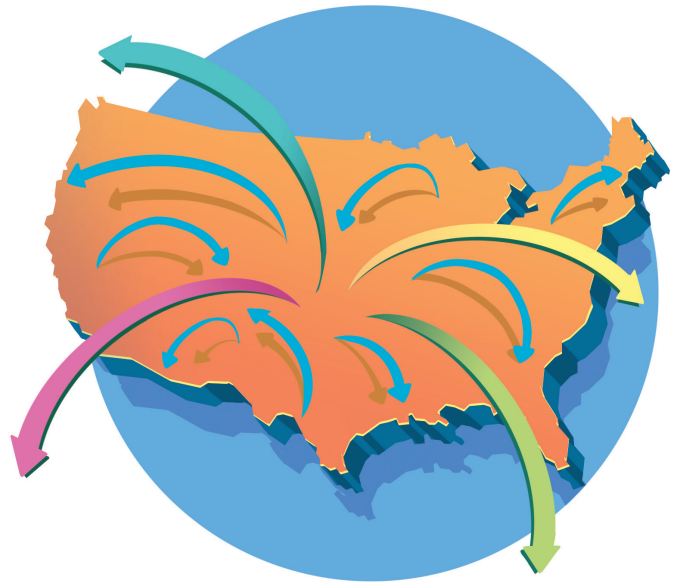
World Health Organization

“The FDA has been really big on Quality by Design. This stems from major initiatives from the ICH International Conference on Harmonization in the 1990s and throughout the 2000s. It’s establishing Quality by Design as the underpinning of pharmaceutical design.”

ASSISTING EFFICIENT VACCINE DISTRIBUTION

The distribution of a temperature-reliant vaccine provides enormous challenges. With ASQE Organizational members like FedEx leading the charge, integral quality practices ensure the supply chain is uninterrupted and mitigate loss.

The success of distribution begins with an efficient transportation process. The quality industry has long impacted best practices in manufacturing and supply chains. In response to the global economic depression in 2008, FedEx implemented a lean management system to enable a smoother workflow and reduce waste.³ The Six Sigma DMAIC methodology of define, measure, analyze, improve, and control of work processes, combined with training in statistical analysis and application, provides organizations like FedEx with the tools to improve their business processes and reduce delivery variation.



Which ASQ technical community members are part of vaccine rollout across the world? Key contributors are:

- Customer-Supplier
- Government
- Healthcare
- Human Development and Leadership
- Lean Enterprise
- Medical Device
- Quality Management
- Six Sigma

United Airlines began transporting doses of the Pfizer COVID-19 vaccine in late November 2020, and American Airlines is doing trial runs and implementing quality measures to ensure it has the capability to successfully transport both the Pfizer and Moderna vaccine.⁴ Gaulding illustrates the intrinsic role of quality in this unique supply chain effort. “Risk management, conceptually, is present throughout the process, from cold-chain transport to administration with hospital systems that needed to be prepared.” Within ASQ, the Customer-Supplier Division continues to develop and educate on concepts like cold-chain distribution validation and customer-supplier qualification quality assessments for risk reduction.



SUPPORTING VACCINE ADMINISTRATION

Due to the historic, quality-driven efforts to produce the vaccine, the United States, among other countries, began administration in December 2020. Quality principles like quality management systems (QMS) supported the healthcare industry in the prioritized vaccine rollout, recipient segmentation and communication. Quality practices have been critical in the design of vaccine clinics, where organization, scheduling and staffing are critically important.

Government and private sectors continue to work together through the administration phase. In May 2020, the U.S. Department of Health and Human Services signed a \$138 million contract with ApiJect Systems America to manufacture more than 100 million prefilled syringes for distribution by the end of 2020, with a goal of over 500 million prefilled vaccine doses in 2021.⁶ ApiJect Director of Quality-Device Eric Schmisser spoke about the importance of quality to the ApiJect BFS Prefilled Injector project for COVID-19.

As the Centers for Disease Control (CDC) centralized distributor for the COVID-19 vaccine, McKesson works with federal, state, local, and tribal health departments, to safely manage delivery and track vaccine allocation.⁵ Though the process continues to be iterated and optimized, their use case presents yet another example of existing quality-centric infrastructure enabling expedited new process deployment.

“What I see are well-oiled quality machines that are leveraging the practices and processes they put together in this time of high need and, through continuous improvement, leveraging the mindsets they’ve built,” emphasizes Genest. “They have overcome their issues and are focused on doing it better and better and better. This is a quality success story in every way.”



Which ASQ technical community members participate in seeing that a vaccine reaches the people who need it? Key contributors are:

- Customer-Supplier
- Government
- Healthcare
- Human Development and Leadership
- Lean Enterprise
- Medical Device
- Quality Management
- Six Sigma
- Team and Workplace



“Quality is not a piece of the jigsaw puzzle along with design, manufacturing, production, and documentation. Quality is the glue that holds all the pieces together.” ⁷

Hospitals, affiliated health systems, and pharmacies are the major administration point of the vaccines. Once received, clinical decision-makers and quality professionals work together to use quality management systems to efficiently handle the vaccination effort and ensure quality is built into this new process that will have to be repeated millions of times. First developed by quality leaders like ASQ Honorary Members Walter Shewhart and W. Edwards Deming in response to industrialization, quality management systems (QMS) have evolved within specific industries and are optimized by organization.⁸ ASQ Technical Communities like the Healthcare Division and the Quality Management Division created monographs to implement best practices and assess the impact of a QMS and related solutions for quality issues affecting the healthcare industry.⁹

QUALITY MATTERS NOW MORE THAN EVER

Quality improvement and assurance are still at the center of historic world events, and ASQ and ASQE continue to support individual and organizational members in addressing the historic COVID-19 public health crisis. The rapid response across industries emphasizes the importance of quality in organizational culture. Genest explained how organizations are looking to give quality a seat at the table from the outset projects, and within pharmaceutical organizations “the CEO and C-suite positions are now very involved in quality.”

For both ASQ individual members and ASQE Organizational members, this renewed prioritization of quality provides opportunities to grow and innovate the way quality is used across industries. ASQ is proud to support the work members are doing in support of the COVID-19 response, and the health and operational successes they enable every day. ASQ Senior Member and Chair-Elect of the Customer-Supplier Division Pam Carvell shared the value she finds in ASQ.

“ASQ gives us a networking resource for an outside opinion. No matter what industry you are in, there is always a standard. I can get a different perspective and that helps me improve.”

In the upcoming months we will share deep-dives into the various quality-connected stages of COVID-19 response and demonstrate how members across ASQ and ASQE continue to define and measure the path to excellence through quality. In short, how dedicated quality professionals continue to make a global difference, seventy-five years after first organizing to achieve just that goal.

1 Centers for Disease Control and Prevention, “Understanding mRNA COVID-19 Vaccines” December 18, 2020. Available at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html> Accessed December, 2020.

2 U.S. Department of Health and Human Services Food and Drug Administration, “Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry,” Pages 2-16. June 2020. Available at <https://www.fda.gov/media/139638/download> Accessed December, 2020.

3 Miller, Bud T. “Superior Lean Strategies in Aerospace” SCM NOW Magazine. July/August 2017. Available at <https://www.apics.org/apics-for-individuals/apics-magazine-home/magazine-detail-page/2017/07/12/superior-lean-strategies-in-aerospace> Accessed December, 2020.

4 Loftus, Peter and Sider, Alison. “United Begins Flying Pfizer’s Covid-19 Vaccine” Nov. 27, 2020. Available at <https://www.wsj.com/articles/united-begins-flying-pfizers-covid-19-vaccine-11606512293> Accessed December, 2020.

5 U.S. Department of Health & Human Services, “Fact Sheet: Explaining Operation Warp Speed”. January 2021. Available at <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html> Accessed January, 2021.

6 U.S. Department of Defense, “DOD Awards \$138 Million Contract Enabling Prefilled Syringes for Future COVID-19 Vaccine,” May 12, 2020. Available at <https://www.defense.gov/Newsroom/Releases/Release/Article/2184808/dod-awards-138-million-contract-enabling-prefilled-syringes-for-future-covid-19/source/GovDelivery/> Accessed December, 2020.

7 ApiJect, “Eric Schmisser Profile,” September 2020. Available at <https://apiject.com/wp-content/uploads/2020/09/Eric-Schmisser-ApiJect-Bio-9.21.pdf> Accessed December, 2020.

8 ASQ, “History of Total Quality Management”. Available at <https://asq.org/quality-resources/total-quality-management/tqm-history> Accessed December, 2020.

9 Quality Management Division “Healthcare Quality and Improvement Committee,” December 1, 2020. Available at <https://my.asq.org/communities/blogpost/view/28/4/1229> Accessed December, 2020.