

OUR SANOFI MANUFACTURING SYSTEM



I. INTRODUCTION

As a worldwide and diversified healthcare leader, we need to continuously adapt our manufacturing capacities and capabilities so we can deliver our wide portfolio of medicines and next generation treatments to healthcare professionals and the patients who need them.

Getting prepared for a successful future demands cutting-edge manufacturing, robust organization and processes, new skills and new ways of thinking. Continuous problem solving skills and agility are also needed to deliver both the large volumes of products needed in established and emerging markets, as well as the small volumes of highly complex products for rare diseases.

To meet these challenges, Sanofi Industrial Affairs have designed since 2011 our very own Lean integrated system, called the Sanofi Manufacturing System, reflecting the company's mindset, culture and industrial heritage.

According to Philippe Luscan, Executive Vice President of Global Industrial Affairs:



"The Sanofi Manufacturing System will ensure that we deliver the best solutions to meet patient needs and by doing so, contribute to our company's growth and success."

II. FUNDAMENTALS AND MAIN PRINCIPLES

The Sanofi Manufacturing System is based on three pillars: our industrial culture, our ways of working, and our operating system, underpinned by performance – all connected to our everyday business and contributing to the delivery of the best-in-class operational performance that our patients expect and deserve.



1. Setting the Scene: Developing our People

- The ecosystem created by the **Sanofi Manufacturing System** focuses on supporting people through training, coaching and professional development to continuously improve industrial processes, eliminate waste (muda) and foster a culture of empowerment and sustainable problem-solving.
- Strong personal involvement and greater autonomy through teamwork support the emergence and continuous improvement of industrial performance standards, shared across the Sanofi manufacturing network.
- A new framework of standardized methodologies, tools and best practice for Sanofi translates into manufacturing excellence. Standardization allows us to speak the same language across the Sanofi network and it ensures that our ways of working are simpler, more robust and more effective.

Ways of Working

The Sanofi Manufacturing System leverages a variety of techniques to achieve daily industrial manufacturing excellence including total productive maintenance (TPM), gemba problem solving (GPS), 5S, single-minute exchange of die (SMED), visual management, +QDCI meetings (focusing on safety, quality, delivery, cost and involvement) and value stream mapping.



Focused on solving a clearly defined issue (with a wide scope of applications: supply chain, quality, finance, Environment, Health and Safety [EHS]), Sanofi Manufacturing System workshops have represented a key vehicle for our continuous improvement model and involve a strong multi-disciplinary teams. They typically include a preparation phase, 3 to 5 days of intensive work, regular follow-up meetings, a final workshop and the communication of achievements and successes. Workshops can be organized at site level or pull together teams from several sites to cross-fertilize expertise and experience ("lab & land" workshops).

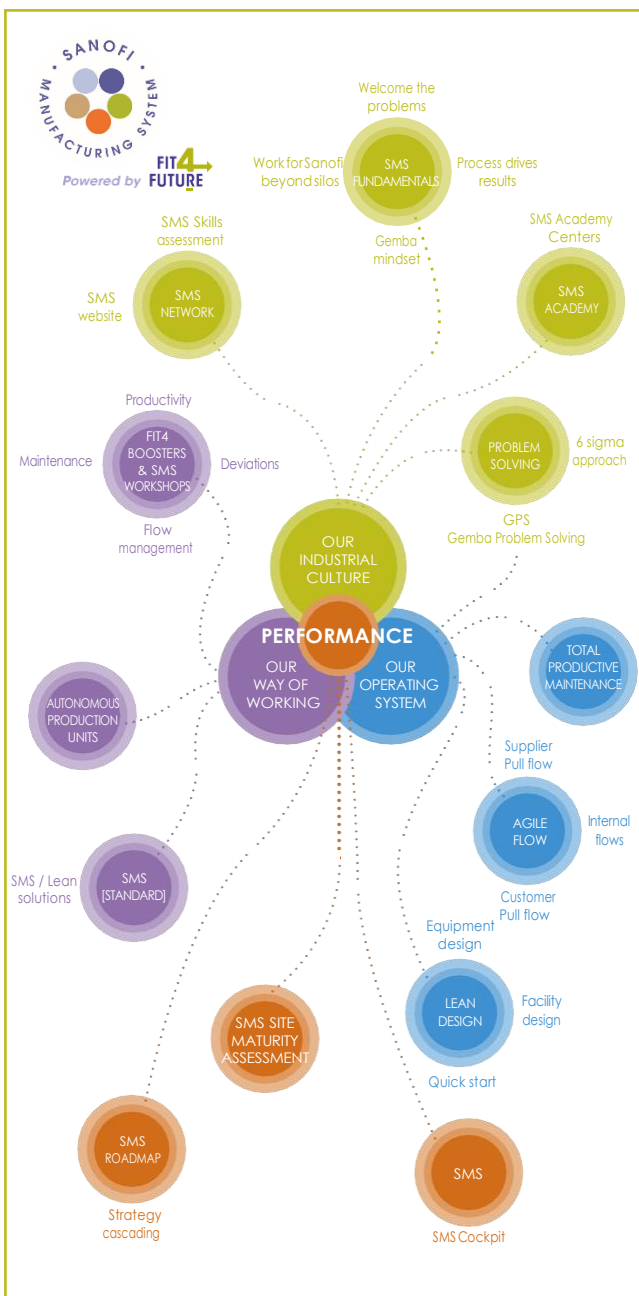


In order to accelerate the deployment of Sanofi Manufacturing System standards, we have also developed our own global transformation program for Industrial Affairs, called Fit4Future.

Typically deployed in a given plant of the Sanofi network over an 18-month timeframe, this program is designed to boost site performance to achieve best-in-class operational excellence and competitiveness. Multiple rapid improvement initiatives, called 'boosters,' roll out in waves to transform processes quickly, revisit organizational models and thereby drive our collective performance. Fit4Future ensures the consistent application of the Sanofi Manufacturing System methodologies and standards, while encouraging a sustainable shift in mindset. To date, 39 sites in 14 countries across the Sanofi production network, have already joined this transformation program.

As much as delivering operational excellence, Fit4Future has proved to be a great opportunity to detect new talent across Sanofi teams. It has allowed

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new Sanofi Manufacturing System standards to emerge (value stream board, daily capacity management and standard agendas) and anchored a sustainable culture of coaching, problem-solving and team empowerment. There is now more fluid information-sharing across plant teams and all levels of management.

In each participating site, Sanofi Change Teams (8-14 employees from different functions and sites, all fully dedicated to Fit4Future), lead the transformation. To date, more than 640 Change Leaders have already been trained on the Fit4Future methodology and behaviours. Change Leaders support site teams to apply new ways of working and Sanofi Manufacturing System core standards, with an emphasis on shifting mindsets to improve performance. The Change Leader role provides a great professional development opportunity with exposure to innovative ways of working and different technologies, as part of transversal international teams.

3. Autonomous Production Units

Autonomous Production Units (APUs) have been created to bring people together from different functions with the aim of achieving higher performance and efficiency. They are organized around a common customer focus (product family or process), common operational goals (priorities/objectives/action plan and key performance indicators [KPIs]), working in a common workspace (obeya room).

APU members are fully dedicated to their APU, but retain a functional link with their head function (quality, supply chain, maintenance etc.). They are based at the gemba level (shop floor) and can therefore make quick decisions at an operational level. Operations management in the obeya room is structured around 10 visually managed processes and tools that address every key aspect impacting the APU performance (key actions, +QDCI, team organization, standard agenda, key problems etc.)

Usually three autonomous levels are defined: level 1 at the gemba (shop floor), level 2 at the production unit, and level 3 at site leadership committee. At each level, the scope of control and functions implicated are defined, along with the related responsibilities and deliverables.

The first APU pilot went live in December 2014. Since then, 8 plants are entirely run through APUSs, with an additional 11 considered in the 2-3 years to come.

4. Operating System

The Sanofi Manufacturing System organizes our end-to-end supply chain and details ways of optimizing performance through just-in-time (JIT) techniques. The standardization process aims to sustain our operating system. Sanofi Manufacturing System standards have emerged from capturing best practices from Lean deployment. They have been further enhanced with the learnings drawn from Fit4Future boosters.

Sanofi Manufacturing System standards, designed to deliver maximum impact on performance, are defined by Sanofi people with shop floor experience. They cover the optimization of resources, managerial attitudes and flows management. The year 2017 focused on development,

design harmonization and pilot deployment through cost-effective channels, such as Fit4Future change teams. In 2018-19, the momentum has continued to grow around these standards leveraging a network of 25 Referents. A second wave of standards is in active preparation.

5. Culture

The Industrial Affairs (IA) Sanofi Manufacturing System program leaders are connected to more than 1,550 Sanofi Manufacturing System Ambassadors in our sites. Each Industrial platform, (Specialty Care, General Medicine, Consumer Healthcare, 3rd Party Chemistry, Vaccines) is supported by a network of full-time Performance Managers at division and site levels.

Our Sanofi Manufacturing System Ambassadors correspond to the Site Senior & Middle Managers who participated in one of the 101 comprehensive on-boarding sessions organized to date. The goals are to foster a full understanding of the Sanofi Manufacturing System mindset and objectives, allowing each site, division or function to design their own Sanofi Manufacturing System roadmap – a 3-year performance plan leveraging targeted Sanofi Manufacturing System solutions. Currently, 95 site leadership teams have been trained and ~20,000 booklets made available worldwide to our people at site ceremonies celebrating the start of the Sanofi Manufacturing System process.

6. Sanofi Manufacturing System Academy

The Sanofi Manufacturing System Academy centers worldwide organize workshops and training sessions, rolling out Sanofi Manufacturing System principles, attitudes, tools and working methods across Industrial Affairs. The Academy curriculum also encourages collective intelligence, a mindset for continuous improvement and enables people to grow by sharing experiences and ideas.

The training model is based on the principle of internal cascading with volunteer trainees being coached and supported to become future trainers. This self-sustaining model is one of the key strengths of the Sanofi Manufacturing System Academy, helping people to master the content of the training programs while developing their soft skills as trainers.

Although Industrial Affairs started this initiative, other Sanofi divisions, such as support functions, Commercial Operations and Research & Development, have applied the benefits of the Sanofi Manufacturing System disciplined management into their own activities.

A network of 9 Lean Academy centers



The Sanofi Manufacturing System Academy has also leveraged **digital** as a key training channel. E-learning components, including videos and presentations are available on the intranet. Digital solutions, which enable e-post-it brainstorm exercises and live challenges among trainees, are also available.

There is a dedicated Sanofi Manufacturing System internal website and a Sanofi Manufacturing System UTube video platform to share best practices. Anyone can upload videos about the Sanofi Manufacturing System which can then be seen, commented on and shared by colleagues worldwide. So far, there are ~1,000 users every month and 300 videos posted online sharing best practices and the outcomes and successes of workshops and events.

7. Our Sanofi Manufacturing System worldwide reach

By the end of 2019, a total of 6,500 Sanofi employees had been trained by the Sanofi Manufacturing System Academy (and 450 e-learners), thanks to 276 internal trainers. These training sessions provide the methodology backbone for the organization of Sanofi Manufacturing System workshops and Fit4Future programs at site level.

On a daily basis, more than 5,000 teams gather in front of the +QDCI boards to discuss and exchange opportunities for improvements and problem solving – from shop floor level up to the Plant Leadership Teams.

8. Sanofi Manufacturing System Certification Program

An ambitious skills certification program with four levels was launched in 2017 to acknowledge every employee's command of the Sanofi Manufacturing System. The formalized scheme involves structured learning and on the job implementation. Each level has clear and objective criteria that have to be met for an individual to be upgraded from one level to the next: Practitioner, Intermediate, Advanced and Champion.

By the end of 2019, ~1,000 Sanofi Managers had already received a certification acknowledging their Sanofi Manufacturing System skills and our first 10 Champions were celebrated.

This program is another illustration of the way that Sanofi is committed to developing teams, and shaping the next generation of manufacturing Leaders, focused on performance to serve our patients.

9. Digital Program: Factory 4.0

The integration of Digital 4.0 aspects into our Sanofi Manufacturing System is already well underway: toward the **paperless factory of the future!**



Priority areas include establishing better data governance and data integrity. We are also developing a range of Digital 4.0 solutions ('digital products') to support and make an even greater impact for our Fit4Future programs at site level. First products cover the fields of eOEE measurement, avoidance of deviations (re-)occurrence, optimization of end-to-end flows, connected maintenance, as well as electronic batch records.

We also want to ensure that our new, major investments are digitally enabled for the future, including a specific focus on engineering paperless factories. Similarly, we are developing a program to leverage Product Lifecycle Management (PLM) solutions to reduce costs and decrease the time needed for product/process development and technology transfers. All this will further increase our industrial network agility and improve our time to market for new medicines.

10. Measuring our Performance

Tracking performance is essential for success. Sanofi has developed an in-house tool, known as 3P (Piloting Performance Plans) to quantify the economic impact of the performance gains generated by our Sanofi Manufacturing System and Fit4Future activities. Instrumental in supporting budget processes, the 3P data are used for evaluating relevant activities in the Sanofi Manufacturing System roadmaps and prioritizing initiatives based on a value-driven approach.