dynamics

ISSUE 37

DESIGN EXPLORATION

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WHEN CFD SECURES THE MANUFACTURING PROCESS OF VACCINES

Bringing Vaccine Manufacturing Validation to the Next Level using CFD: Creaform Upgrades the Regulatory Compliance Process of Pharmaceutical Environments

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Creaform

Creaform was asked to assist in the design of a cleanroom, by performing a complete 3D reconstruction of the geometry of the room, and using this to carry out detailed CFD simulations. The cleanroom in question is used in the manufacturing of influenza vaccine, and the aim of the study was to design an efficient aerodynamic barrier that would mitigate the risk of contamination. The demonstration was convincing and CFD simulations shed light on phenomena that traditional smoke tests, still used for regulatory compliance of pharmaceutical environments, had never been able to resolve before.

INTRODUCTION

The pharmaceutical cleanroom in this study is a critical environment requiring a high level of protection against contamination. While the cleanroom itself is a grade B environment, the interior of the RABS (Restricted Access Barriers) is protected with screened barriers and HEPA (High-Efficiency Particulate Air) clean-air filtration, such that it is rated as a grade A critical zone. The vaccine filling machine had to be incorporated in the RABS, leading to many specific flow interactions which could not be predicted prior to installation, neither by the manufacturer nor the integrator.

The RABS provide vaccine protection against contamination using a physical and aerodynamic barrier. The extent of separation between the process and the contamination sources, like people, determines the grade level of the protected zone. Grade B environment is already a decent class of cleanroom, and further zoning with restricted access barriers, like the glass doors with gloved access, defines a grade A critical zone.

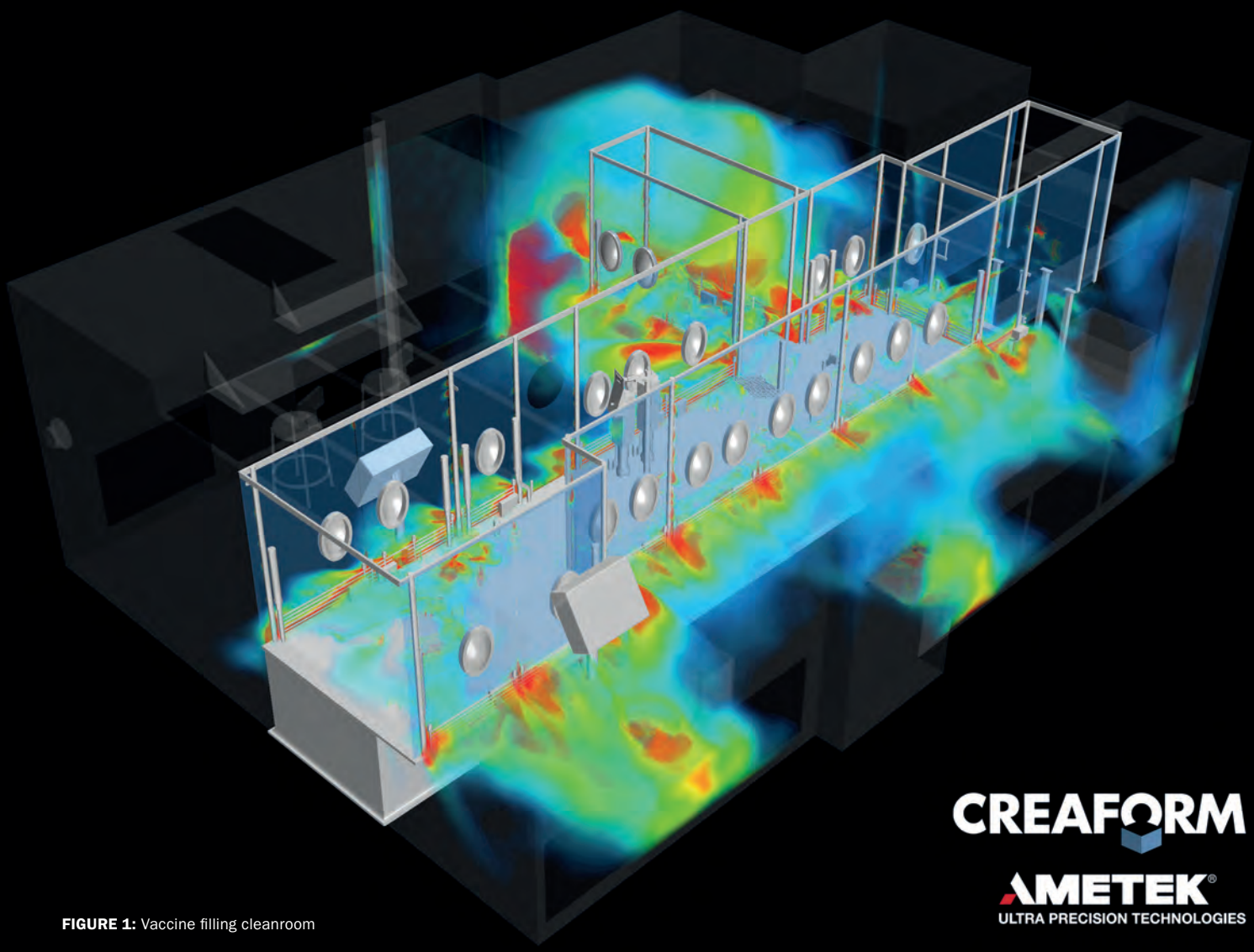


FIGURE 1: Vaccine filling cleanroom

FIGURE 3: Hexahedral mesh of vials conveyor

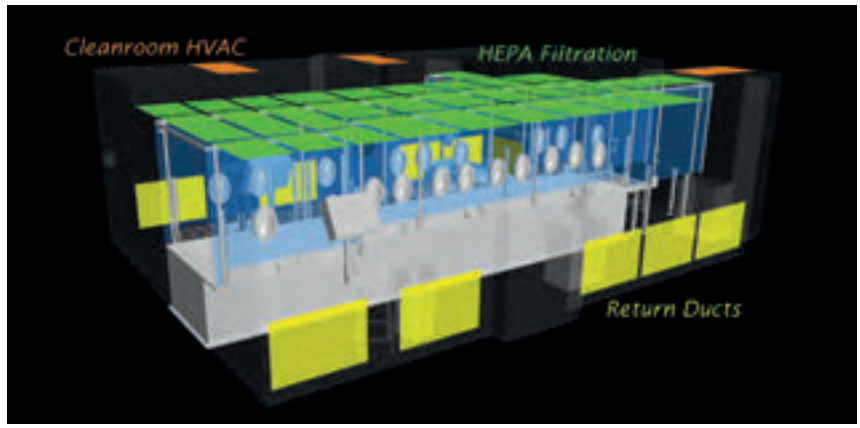


FIGURE 4: Principal boundary conditions

Creaform provides, amongst other services, consultation in numerical simulations and uses STAR-CCM+® in its software arsenal as it allows to quickly treat about any geometry, including raw scans. Our experts can work around with the scans and any other available data to numerically reconstruct the geometry and then perform the CFD simulations, cutting down costs and intermediaries.

SIMULATIONS

Precise and representative boundary conditions are critical for the cleanroom simulation. They were carefully determined using very recent data acquisition:

- Laminar flow equipment performance evaluation providing air velocity profiles for each diffuser of the HEPA filtration system;
- Ventilation balancing measurements for the HVAC system including return ducts;
- Precise pressure gaging in adjacent rooms for secondary air flow rates through wall openings for conveyor and through the door contour.

Turbulence modeling was achieved with the RANS approach and more specifically with the SST (Menter) k-omega model, thus limiting the results to steady state. The All y+ Wall Treatment was used because many near wall cells fell within the buffer region of the boundary layer. The control over the entire surfaces to force viscous sublayer resolution was computationally expensive and judged unnecessary. Indeed, calculation of viscous forces is not required and flow separation occurs at cutting edges, so its prediction is trivial. Consequently, the mesh is polyhedral and does not make use of prism layers. The prioritized cell refinement was the one allowing to capture the surface details of the machine components, resulting in a cell count of 5.6 million for initial runs (setup check and initial solution) and of 18.4 million for final runs. Simulations made use of the coupled flow model with a 2nd order discretization.

RESULTS

OVERALL PRESSURE DISTRIBUTION

Ideal flow conditions just above the conveyor level consist of a perfectly vertical flow. Pressure distribution in the horizontal plane is thus very important and must be as uniform as possible inside the RABS. The first CFD simulation of the cleanroom showed a small pressure gradient that was sufficient to induce a longitudinal component to the velocity vectors inside the RABS. Laporte engineers designed deflectors to redistribute the pressure in the capping section and removed the partition that provoked a pressure increase in the vials accumulation section. Combined with the modular adjustment of the HEPA filtration, these modifications significantly improved the pressure distribution in the RABS (see figure 5). The CFD simulation correlates well with the smoke tests performed with the new design and confirmed the improvement efficiency.

TRANSVERSE FLOW

With the longitudinal flow corrected, Laporte and Creaform focused on transverse velocity components in the vicinity of non-sterile machine components. The CFD simulations highlighted two similar undesired situations: one around the needles holder and one around the capping arm. Both components are non-sterile and the air draft from underneath the physical barrier induces a significant transverse velocity component. As can be seen in Figure 6 (a), this phenomenon drives particles in contact with the arm directly toward the vials that are conveyed at the level of the toothed plate. The aerodynamic deflector visible on Figure 6 (b) was tested in simulation and provoked the shift of the air draft towards the machine floor. It caused the streamlines in the vicinity of the arm to reach the underside of the conveyor, keeping the potentially contaminated particles far from the vials. A similar defector was used at the level of the needles holder. Once designed by Laporte and outsourced for machining, these deflectors were tested in situ with smoke and turned out to perform very well as predicted by the CFD analysis.

IMPINGING FLOW

A third undesired situation addressed by CFD simulations is the one caused by impinging flow on non-sterile surfaces: the accumulation table and the conveyor discs. In both cases, the parts expose a horizontal surface directly to the vertical flow, inducing stagnation points and undesirable vortices.
On the table at the beginning of the production line, opened vials accumulate

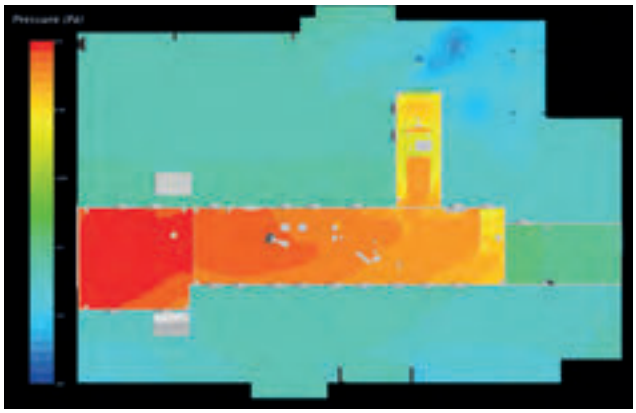
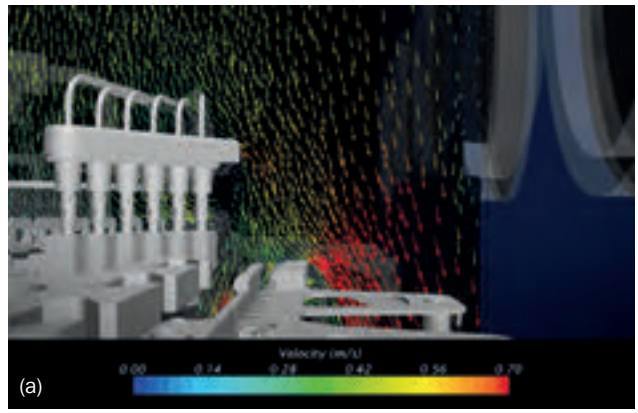


FIGURE 5: Pressure distribution in horizontal plane – before (above) and after (below) design adjustments



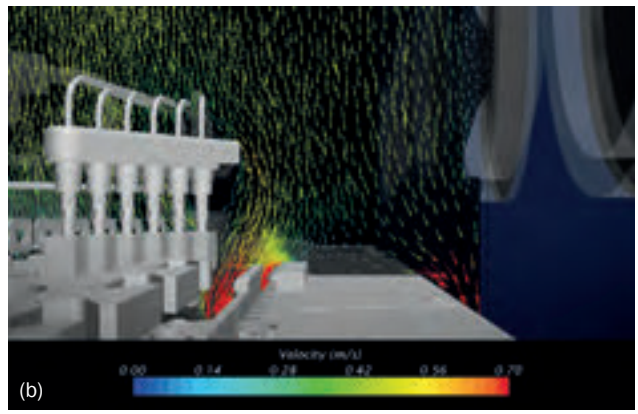


FIGURE 6: Velocity vectors in section plane at capping arm elbow - original design (above), modified design with aerodynamic deflectors (below)

"Creaform's integrated solutions of scanning, CAD reconstruction and CFD analysis gave visual and precise answers about intangible air flow questions."

GILLES GRENON
Laporte Consultants Inc.

and form a circular pattern near the exterior edge of the table. This table is designed with a central hole, allowing for a proportion of the impinging flow to evacuate without touching the vials. Nevertheless, some streamlines evacuate through the exterior edge, passing through a series of vials as can be seen on figure 7. Many fixes to decrease head losses for the flow through the central hole have been tested in simulation with mixed success. The attention was then focused on determining the actual risk of contamination for the evacuation through the exterior edge, and a particular simulation of the flow around the vials was performed. This detailed simulation, with actual vials modeled, used the global simulation fields to determine boundary conditions. It showed that in steady-state, the entire flow in contact with the table would evacuate through the vials' shoulders (see figure 8), thus limiting the contamination risks. Laporte also proposed a specific cleaning procedure for the accumulation table.

As for the non-sterile conveyor discs, they would induce a stagnation point surrounded by vortices that would eventually transport particles over the vials path. Thus, their initial design as solid discs was questioned and Laporte ultimately remanufactured the discs and added holes, allowing for a much better evacuation towards the machine floor. The modification was tested with the CFD model and with smoke ejections and both methods confirmed the suppression of the issue.

CONCLUSION

The project was a convincing demonstration of the complementarity of the reverse engineering solutions and CFD capabilities of Creaform's Engineering Services team, equipped with STAR-CCM+®. The project was also a clear demonstration of the innovative mind of Laporte, who adopted CFD in its cleanroom commissioning in order to gain predictive insight to complement the traditional smoke tests. The CFD results presented here are currently used in combination with the smoke test videos to demonstrate the effectiveness of the aerodynamic barrier in front of regulatory agencies. So far, the feedback is very positive as CFD really helps to visualize the flow features. It is Creaform's will to make CFD a prevalent tool for future pharmaceutical production lines.

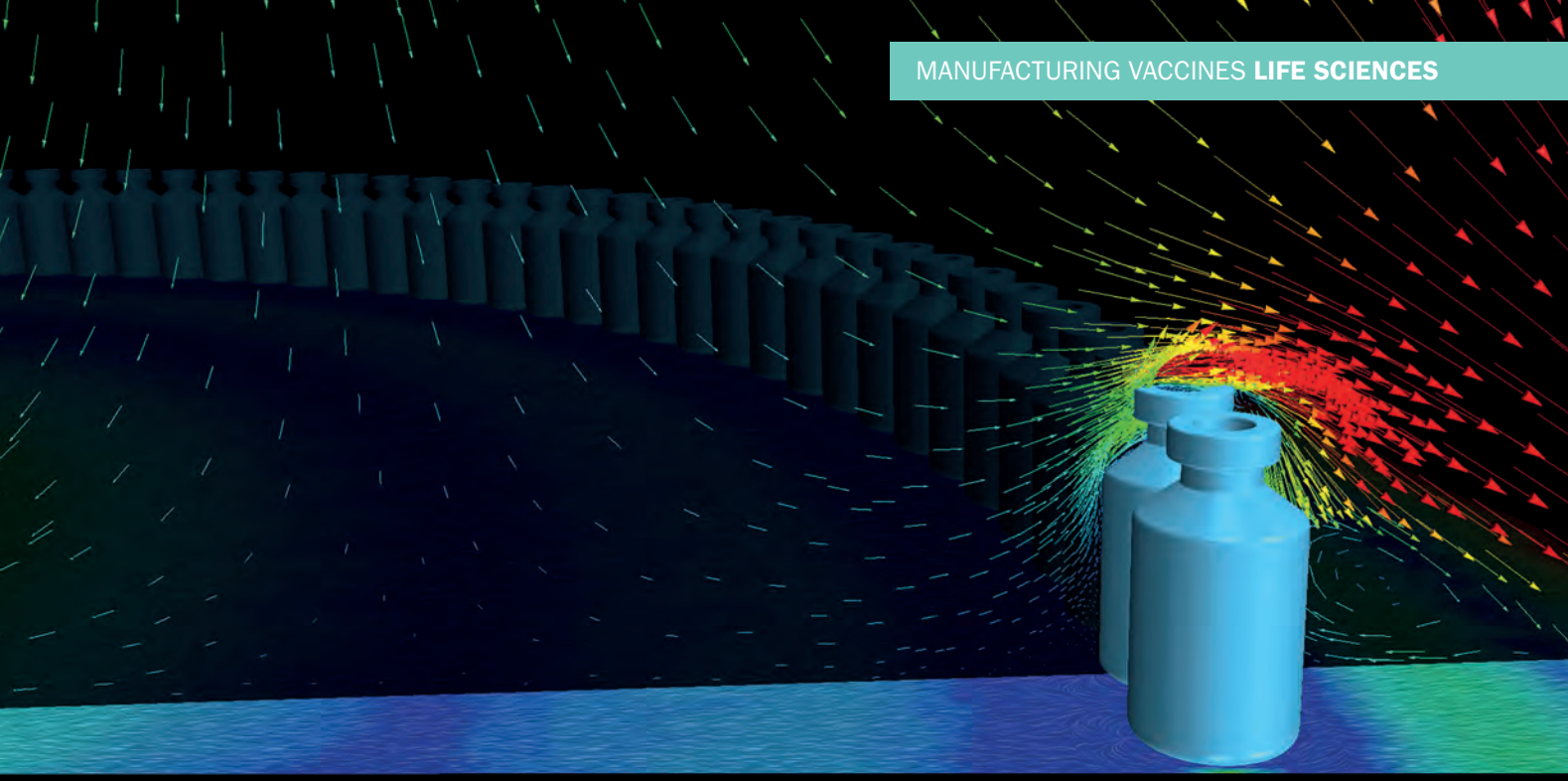


FIGURE 7: Impinging flow on accumulation table

FIGURE 8: Streamlines in close contact with the table and evacuating through the vials shoulders