In process cleaning of open devices during assembly

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This article is based on a master thesis conducted at McNeil AB in 2013. The task was to look at different ways to make sure that the vials of Nicorette Mouth Spray and Nicorette Nasal Spray were clean before they were filled with the nicotine solution. In the end a prototype was constructed for this task.

McNeil AB is a company within the Johnson & Johnson concern. Their main product at site is Nicorette. McNeil AB has found some particles inside a few vials and after analyzing the particles with Near IR it was found that they were corrugated paper and plastic splinters, probably leftover scraps from the vials themselves. With this in mind McNeil AB would like to have a system that cleans and/or checks the vial prior to filling.

The ideas to how to clean the vials were limited to no contact cleaning, due to the GMP (Good Manufacturing Practice) rules of the pharmacy industry. With this is mind the only solution to clean the vials were with pressurized air or vacuum. There was also a question if there was some way to detect the contamination after cleaning to really see if it had been cleaned. An inquiry was issued to the Johnson & Johnson's Engineering Network, a secluded group of engineers from different companies of the concern, about ideas on how to solve this problem. From the replies there was an engineer from South Korea who recommended a dual pipe with both pressurized air and vacuum. This idea was applied to the solution after some testing.

As the testing progressed the test setup developed and this gave as results what kind of diameter, depth, pressures and equipment to be used in the final prototype to be used in the production line. When the testing was done the equipment needed was ordered from Logicsystem AB and a vacuum generator from FESTO.

Figur 1. The prototype of the solution.

In parallel to the testing a model of the production line and a model of the prototype were made. A model of the production line of the mouth and nasal spray was necessary to get a feeling for how much space there was to implement the cleaning solution.

When both the model was finished and the products had been delivered these were sent over to the workshop and to the electrical

department of McNeil AB to get the prototype built, see figure 1.

To be able to implement and install the prototype in the filling machine different documents such as Risk Analysis and (URS) User Requirement Specifications were setup to prepare this. These documents were also needed to make sure that the GMP requirement was fulfilled.

The cleaning ability of the prototype was tested out with 400 vials. Each vial was prepared with 1 piece of corrugated paper and 1 piece of plastic. Out of these 400 vials 395 were successfully cleaned. This gives a 98.75% rate, which is what could be expected when implementing the prototype in the filling machine.

In the end the prototype fulfilled the URS, GMP and performed cleaning with high accuracy as was desired.