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STANDARDIZATION OF THE MANUFACTURING PROCESS OF EXCIPIENT ALIQUOTS TO COVID-19 VACCINES

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Introduction

Since the beginning of the vaccination campaign in our hospital, cases of anaphylaxis are reported. Articles published in February 2021 indicate a prevalence of around 1 issue per million doses[1]. Subsequently, our production unit was then asked to evaluate the effectiveness of prick tests or aliquots as a screening tool for patients at risk.

Objectives

Implementing **a standardized manufacturing process** for excipient aliquots for COVID-19 vaccines and integrating these new demands into routine activity.

Material and method

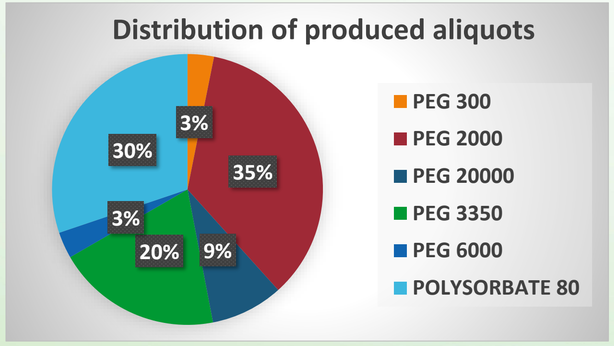
The aliquots were manufactured under horizontal laminar airflow hood (BPF Class A), in a controlled atmosphere zone of GMP Class C piloted by a gravimetric software (BD CATO®)

1) Weighing of raw materials (PhEur quality) with an analytical balance
2) Dilution in 0.9% NaCl
3) Mixing under magnetic stirring
4) Sterilization of the preparation by filtration at 0.22 µm
5) Packaging in microtubes and labeling in accordance with current GMP standards

Results and discussion

Between february 2021 and August 2022: production of **37 batches** or **656 aliquots**

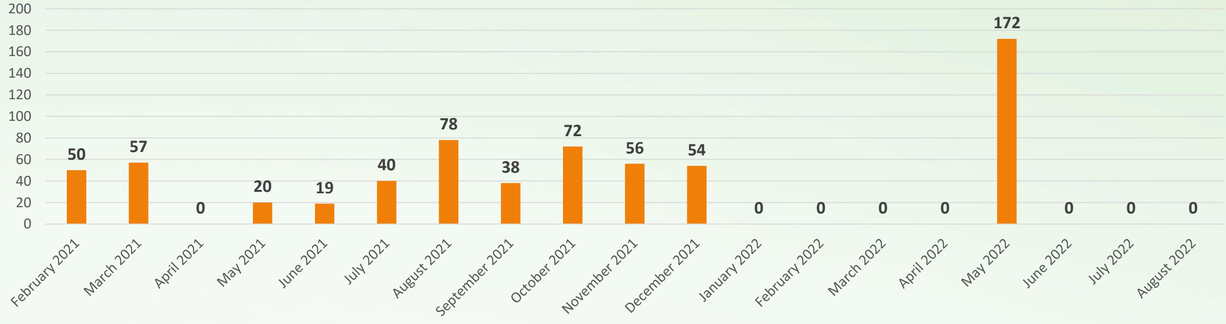
106 h of work for operators
25,75 h of work for pharmacists



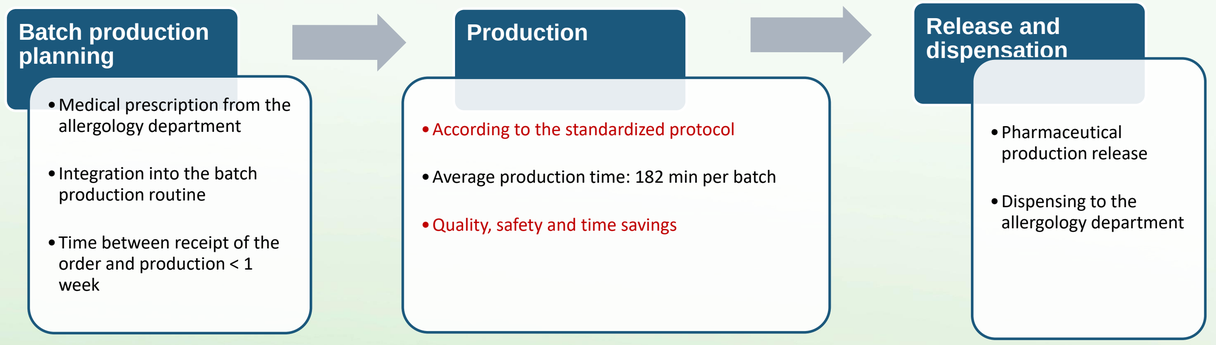
Conclusions

Thanks to the development of a production method, **the quality** (raw materials) and **the safety** (dose and microbiology) of the aliquots could be guaranteed and the demands were successfully integrated into the routine activity of our pharmacy. These new requests have introduced a new field of expertise and specialization to the production unit.

Number of aliquots produced after implementation of standardized manufacturing process



Integration of aliquots into routine activity



Références

1. Shimabukuro TT, Cole M, Su JR, Reports of Anaphylaxis after Receipt of mRNA COVID 19 Vaccines in the US December 14, 2020 January 18, 2021. JAMA 2021

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