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DRUGCAM®, a video analysis system: Its impact on risk management in cytotoxic drug production units

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Background: The Drugcam® (DC®) "in process" monitoring system was implemented in the unit in 2018 as a corrective action in response to unacceptable failures identified during a risk analysis.
Objective: Identify and assess the impact of DC® on the production process for injectable chemotherapies away from its facility.

Methods

Creation of a working group and a risk assessment grid → Identification of risks and ranking according to their level of criticality → A comparison was made of 3 risk analyses carried out at different times (before, during and after the installation of DC®)

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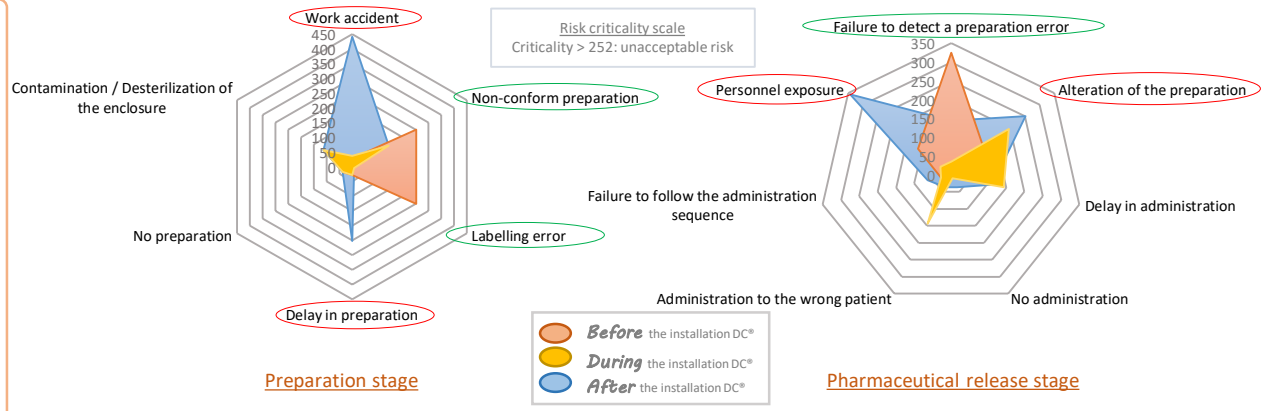
Analysis of anomalies identified by DC®:
Creation of a glossary, study of their incidence and root causes
Study period: 8 weeks
➔A total of 4316 preparations including 896 preparations with anomalies

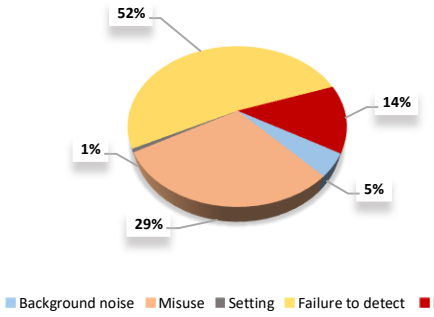
A risk analysis FMECA CARTORISK® at a distance from the installation of the DC® tool

Comparison focusing on *the pharmaceutical preparation and release stages* (impact of DC®)

Viewing the 896 videos of preparations with anomalies

Results





1037 anomalies identified, including 142 preparation errors (error rate of 3.3%)

At a distance from the installation, the FMECA shows a different distribution of criticality compared with previous analysis:

✓ 3 unacceptable risks controlled, such as the risk of labelling errors, the risk of non-conform preparation and the risk of failure to detect preparation errors during release.

✗ 3 uncontrolled risks, including a risk that was not well known, linked to the poor management of leftovers, with a risk of altering the preparation, and two new risks, such as the lack of knowledge about occupational exposure to cytotoxics (linked to equipment and new handling practices) and the emergence of misuse, which could lead to delays in preparation. Analysis of the videos shows that misuse is the second most frequent anomaly (29%), including non-compliance with the DC Assist® scenario, incorrect presentation of objects to the camera, and a deterioration in good tray control practices, with a risk of losing production prioritisation as a result of the dematerialisation of the production sheet.

Conclusion: DC®, by reducing the criticality of the risks identified prior to its implementation, makes the injectable chemotherapy preparation stage safer and meets the initial objectives. The changes in practice associated with the tool have brought to light new risks that had not been identified at the time of installation. The way DC® works makes it possible to objectify the frequency of risks. Corrective actions need to be put in place within the unit, such as assessing exposure to cytotoxics and working on good practices for using the tool in the form of practical exercises.