



Using Quality Risk Management in the Plantibody HB-01 Manufacturing by Transgenic Tobacco Plants for Vaccine Production

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SUMMARY. The production of biopharmaceuticals by transgenic plants is a promising choice to achieve the multi-kilogram amount of products needed to treat many human diseases. However, this scientific field is still lacking of approved specific guidelines regarding points to consider for manufacturing and application of these products. In such sense, the implementation of new manufacturing processes and quality systems using the *quality risks management* is recognized as something of prime importance in the current pharmaceutical industry. In this work, we summarize the application of the FMEA method to design the manufacturing process of a plantibody, employed in the hepatitis B vaccine production to ensure the vaccine high quality.

KEY WORDS: Biopharmaceuticals, Hepatitis B vaccine, Plantibody, Quality risk management.

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