Qualification and Continuous Validation of a Compressed Air System Used in the Biotechnological Industry

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Abstract

Compressed air is widely used in the biotechnological industry. Impurities in compressed air may jeopardize intermediate and final products leading to quality deterioration. Qualification and validation of compressed air systems is mandatory to obtain a compressed gas with all quality attributes. This study aims to show evidence in qualification and continuous validation of the compressed air system of a production plant that produces multiple active pharmaceutical ingredients obtained by biotechnological processes such as: recombinant hepatitis B surface antigen, human epidermal growth factor, granulocyte colony stimulating factor and p64K-r within others. The results demonstrate that the total hydrocarbon content in all determinations were ? 0.1 mg/m3. In all analyzed samples, dew point temperature values were below 7 °C showing the stability and quality of the distributed compressed air. Compliance to specifications established by ISO guide 8573-1:2010 for non-viable particles was also required. In addition, a microbial growth level below 2 CFU/m3 was detected confirming the system reliability. All active pharmaceutical ingredients fulfilled the quality specifications, which demonstrate the non-deterioration of the products. In conclusion, the qualification and maintenance of the validation status of the compressed air system according to international standards ISO 8573.1:2010, about ensuring the quality and purity, class of 1.5.2, are in agreement with current biopharmaceutical industry requirements.