

Quality Management in Leishmania collection of the Oswaldo Cruz Institute (CLIOC/IOC/FIOCRUZ)

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Abstract:

The *Leishmania* Collection of the Oswaldo Cruz Institute (CLIOC) started its activity in 1980 with the support of the Oswaldo Cruz Institute, the Oswaldo Cruz Foundation and the World Health Organization. CLIOC is registered at the World Federation for Culture Collections (WFCC – WDCM 731), and is a partner of the Global Biological Resource Centre Network (RBC's) demonstration project. *Leishmania* is a protozoan parasite responsible for a neglected disease occurring in many parts of the world. Over the past years, CLIOC has accomplished an essential and dual role for science and society in providing both a foundation of knowledge about the host and geographic distribution of parasites and in contributing to the resolution of a number of real problems facing the epidemiology of leishmaniasis. The maintenance of *Leishmania* axenic culture collection is important to support public research and educational institutions since it provides cultures that are used for: producing DNA and/or antigens used in molecular and immunological tests for diagnosis, respectively; differentiation of clinical isolates using biochemical and molecular techniques and elucidation of differences useful as molecular epidemiology tools; identification of potential therapeutic agents, improving advances in chemotherapy and producing vaccines. A steady increase of requests to CLIOC resulted in the establishment of a Quality Management System (QMS), capable of managing the transition from a culture collection to a BRC. This addressed human resources, implementation and maintenance of a QMS and Biosecurity, improvement of the effectiveness and efficiency in performance for services and research development. Management and documentation of data in accordance with rules and standards that ensure their safety, accessibility, quality, longevity, integrity, and interoperability were key points within this process. Nowadays, CLIOC is operating in accordance to ABNT NBR ISO/IEC 17025, and in adherence to the guidelines of "Organization for Economic Co-Operation and Development (OECD). CLIOC has a team of professionals and collaborators qualified as well as a range of facilities: laboratory for research on leishmaniasis and *Leishmania* biochemical and molecular identification, rooms for biological material reception, culture and cryopreservation facilities and an office for the QMS and Information, fully adequate to ensure the quality of their services. CLIOC is inserted into the institutional policies of Quality, Environment and Biosecurity and the Program Cleaner Research (P+L-FIRJAN), that meet all requirements for the management of chemicals and biological wastes through the application of procedures for their pre-treatment and disposal, certified by the Quality in Environmental Management Internal Commission (IOC/FIOCRUZ).

Key words: Leishmania collection, Quality Management, RBC