ISO 9001:2015 Certification of the Allergy Laboratory

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To the Editor:

The Allergy Laboratory at Hospital Universitario La Paz, Madrid, Spain recently achieved certification under the ISO 9001:2015 standard. The certification has enabled us to better manage our processes and align our strategic direction with the needs of the Allergy Department. ISO 9001:2015 not only adds value to our laboratory, but also strengthens our commitment to delivering high-quality services in a more efficient, patient-centered manner, thus ensuring the safety and the quality of care delivered [1-2].

The purpose of this letter is to introduce our laboratory, share insights into the certification process, and highlight the benefits this has brought to our operations, with the goal of encouraging and facilitating certification for other allergy laboratories.

Our laboratory plays a crucial role in the Allergy Department, providing essential support to clinics, day hospitals, and the Severe Asthma Unit, which is accredited by the Spanish Society of Allergy and Clinical Immunology (SEAIC) [3] and the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR). The laboratory's activities are structured around 2 core functions, namely, clinical support and management of severe asthma. Each function encompasses specific processes, which are illustrated in the Figure.

The scope of our ISO 9001:2015 certification covers several critical areas of laboratory activity:

- Preparation of food extracts and medications for intraepidermal, intradermal, and epicutaneous testing.
- Preparation of blinded food samples for oral challenge tests.
- Personalized clinical allergy assessments to support diagnostic processes.
- Processing and maintenance of clinical samples for biobanking.
- Processing of induced sputum samples for asthma phenotyping based on inflammation patterns, aiding in the diagnosis and monitoring of severe asthma patients.

In addition to these clinical functions, the laboratory is actively involved in research on allergy and severe asthma and provides training in allergology techniques for resident physicians and senior laboratory technicians.

The certification process took approximately 1 year and was divided into several key phases. Initially, we conducted a thorough, critical analysis of our laboratory operations,

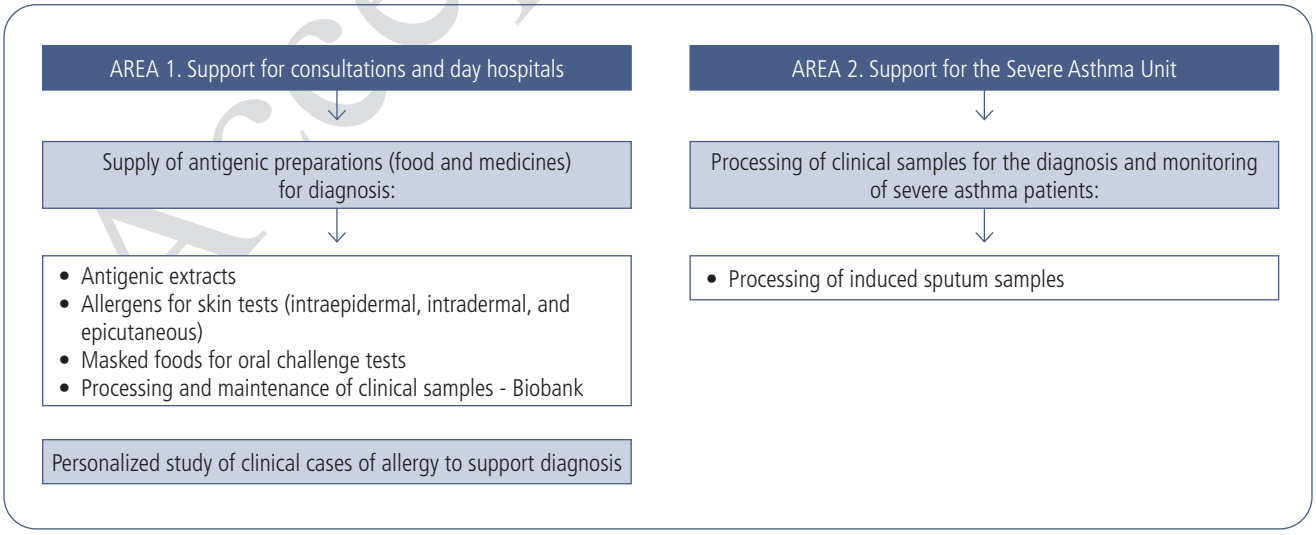

Figure. Operational processes of the Allergy Laboratory.

identifying both strengths and areas for improvement. Following this, we reviewed and updated all our laboratory procedures, documenting them as standard operating procedures, in which we formalized how processes should be executed and clarified roles and responsibilities.

A significant aspect of the requirements for the ISO certification involved the establishment of quality indicators for each process carried out in the laboratory. These indicators enabled us to measure how the processes were progressing and to detect faults that would have gone unnoticed before implementation. In the formulation of each indicator, the measurement frequency of each process is also defined, for example, quarterly or half-yearly, and incidents are recorded during this period. The detection of a problem in a process leads immediately to a definition of nonconformity and requires the implementation of a corrective action.

In some processes, the basic quality indicator we defined was the percentage of incidents recorded in relation to the total number of preparations. For example, in food extracts, we detected a gradual increase in the percentage of incidents related to failures in the vacuum freeze-dryer system, which reached 50%. This led the hospital to replace the old equipment with new equipment as a corrective action. In induced sputum sample processing, we established 2 quality indicators: the basic indicator, ie, the percentage of incidents with respect to the total number of samples processed; and a second indicator, ie, the percentage of samples with no results achieved compared to the total samples processed [4]. This was because the induced sputum technique is limited, as it depends on the cooperation and medical condition of the patient, from whom respiratory effort is required to obtain the cells. In our experience, the percentage of samples without results compared to the total samples processed was 37.4% (obtained from our results in 3 studies), which we set as a reference value.

Moreover, the daily measurement of the temperature of the refrigerators and freezers using control probes enabled us to detect failures in some devices that would have previously gone unnoticed.

The certification process further formalized the roles of the responsible practitioner and laboratory technician by documenting their continuing training plans. It is also important to note that our technicians are accredited food handlers, in compliance with Regulation No. 852/2004 of the European Parliament and of the Council of 29 of April 2004 on the hygiene of foodstuffs.

Finally, we conducted a risk and opportunity analysis. This enabled us to identify strategic future priorities, such as the implementation of the laboratory's digitalization process, which was one of the needs highlighted during the analysis.

The certification process was satisfactory, although it presented a significant challenge in terms of the considerable time and effort required from all the laboratory professionals involved. The primary practical difficulty was completion of all certification tasks without compromising the laboratory's ongoing health care operations. The process is now advancing to the next challenge, namely, implementation of the digitalization process.

As per comments from other authors, the decision to undergo control and evaluation of a quality system such as the ISO standard is a voluntary process that requires the laboratory to be bold enough to submit to external quality assessments and then to commit to correcting or restructuring irregularities or anomalies detected during the audit if the standards are not met [5].

In conclusion, obtaining the ISO 9001:2015 certification has significantly enhanced the quality and efficiency of our laboratory. We hope that our experience may serve as a model for the development of allergy laboratories elsewhere, ultimately supporting the work of allergy departments and benefiting patient care.

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Conflicts of Interest

Dr Quirce has been on advisory boards for and has received speaker's honoraria from ALK, Allergy Therapeutics, AstraZeneca, GlaxoSmithKline, Chiesi, Mundipharma, Gebro, and Sanofi. The remaining authors declare that they have no conflicts of interest.

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