

# GOOD RESEARCH PRACTICE IN DRUG DISCOVERY

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## INTRODUCTION

The field of Drug Discovery in which Axxam is involved does not include a certified Quality System such as GLP, for example. Nevertheless, in 2006 Axxam decided to implement a voluntary Quality System that put all Facility, data recording and archiving under control, taking inspiration from GLP.

The reasons that led Axxam to focus on quality are mainly linked to the desire to provide Clients with products, whether engineered cell lines or proteins or data, that are accurate, valid, and reproducible. Furthermore, companies that turn to Axxam to obtain services require increasingly higher standards and Quality is essential to remain competitive in the market.

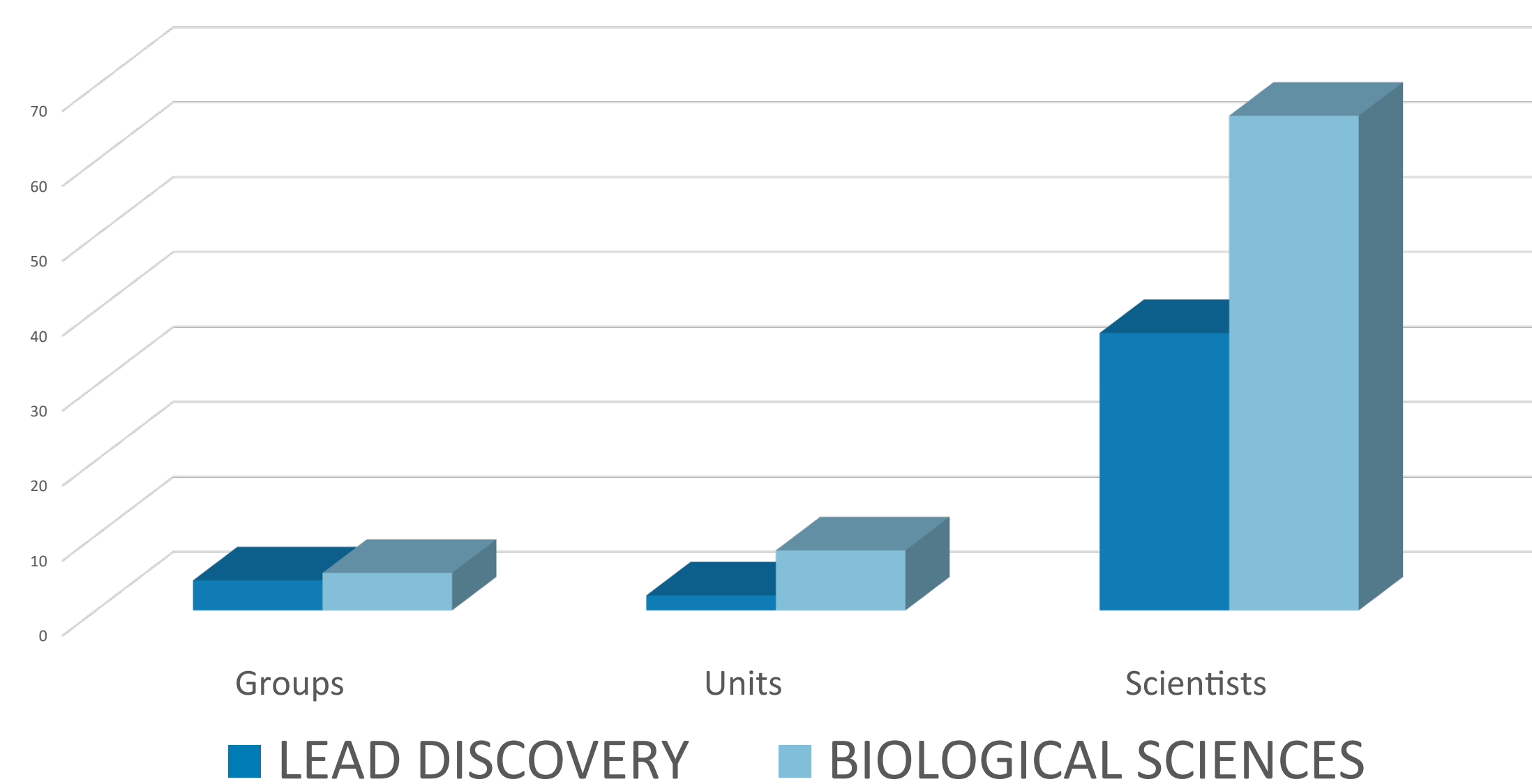
**2** operational sites  
**3** industry segments  
Pharmaceutical (91%)  
Flavor & fragrance (6%)  
Agrochemical (3%)

**165** people  
**71%** women / **29%** men  
**41** average age  
**85%** within 30-55 years old

**60%** PhD  
highly qualified scientists

## AXXAM LABS BY NUMBERS

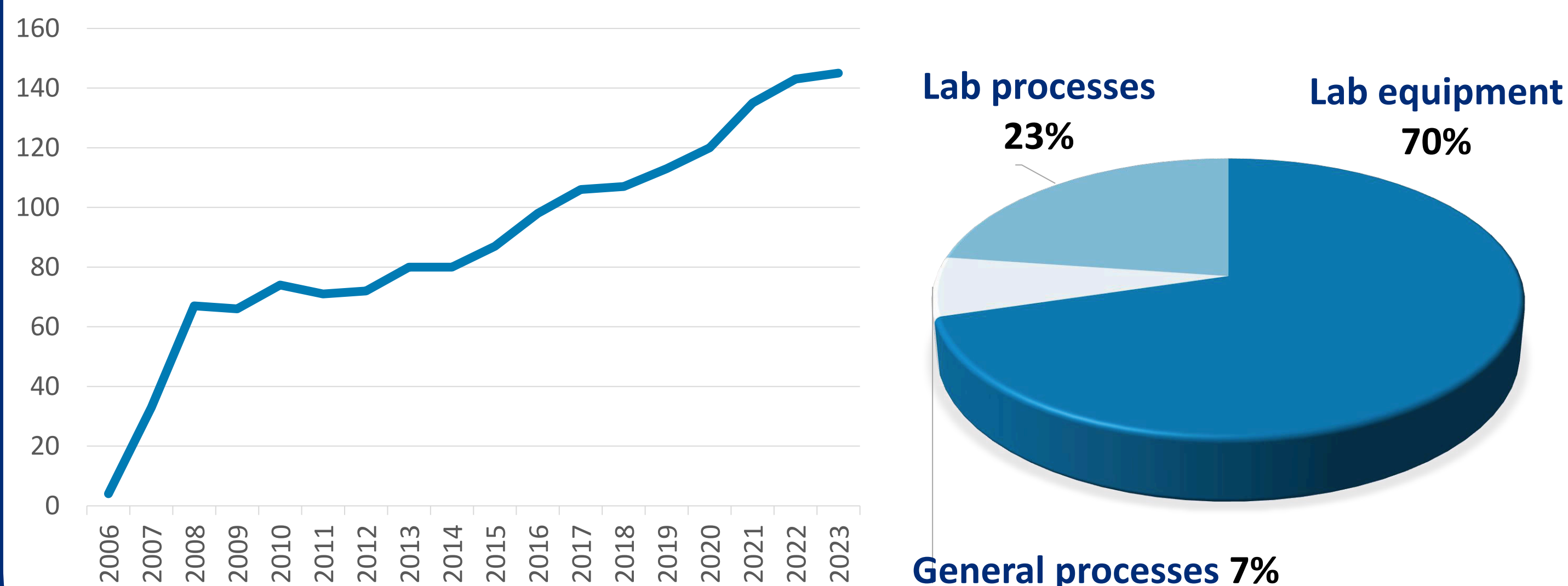
DEPT	Groups	Units	Scientists
LEAD DISCOVERY	4	2	37
BIOLOGICAL SCIENCES	5	8	66



## STANDARD OPERATING PROCEDURES

Axxam's internal quality system is based on SOPs and takes into consideration: the management of all equipment, calibration check of critical instruments, management of all reagents and solutions present in the Company's laboratories, recording of training, drafting of Company CV, tracking of all contents of refrigerators and freezers, including the nitrogen container where the final clones and cell lines are stored. Laboratory operating methods, such as cell line management, have also been standardized.

In 2024 AXXAM has 145 SOPs in place.

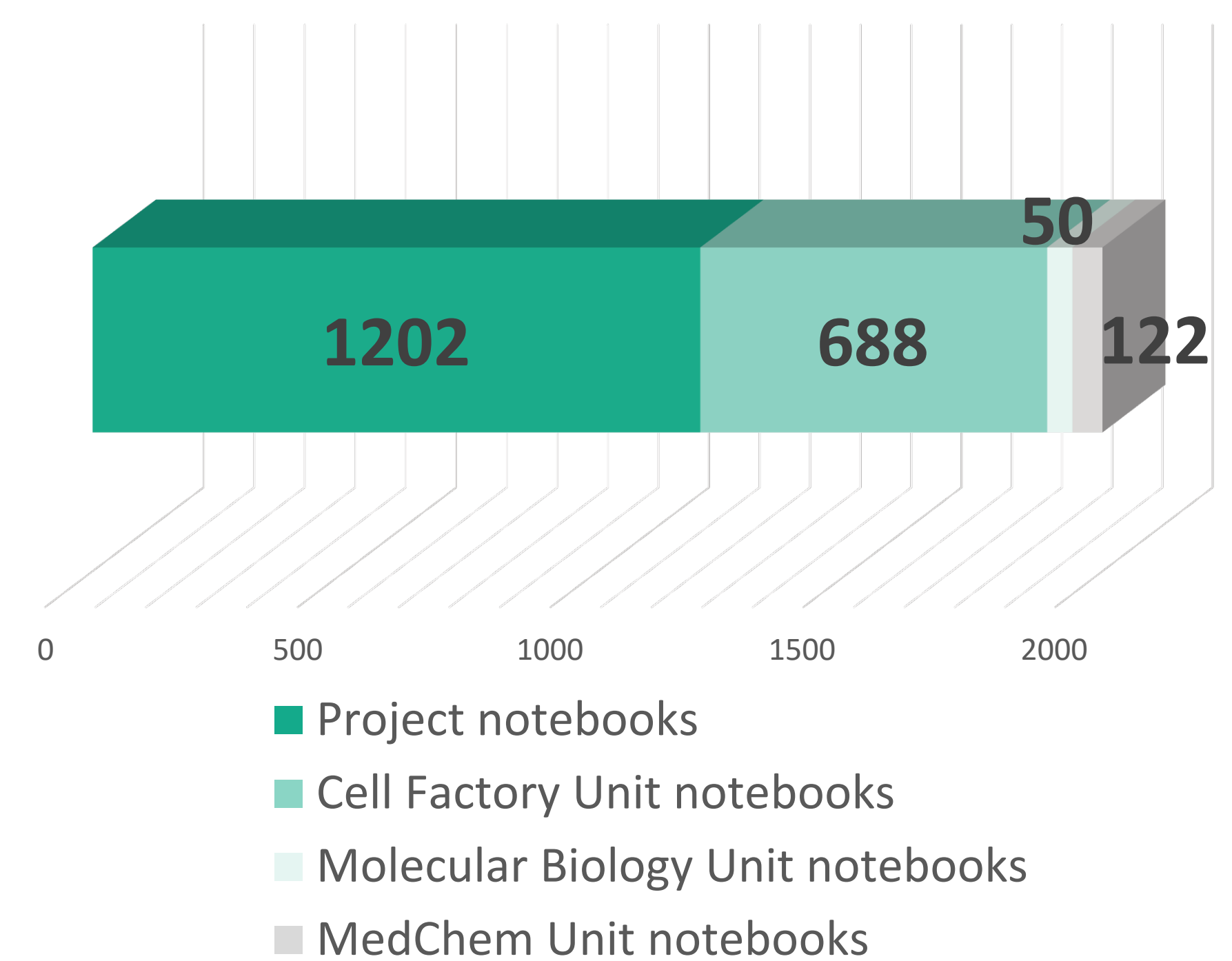


## DATA REGISTRATION & ARCHIVING

About data recording Axxam fully replaced paper notebooks with electronic laboratory notebooks (ELN) by Revvity Signals Notebook software. *Signals Notebook* is a 100% cloud-based platform and can let you connect and share data with colleagues and other collaborators. Signals Notebook enables research teams to work in a new, more connected, and collaborative manner to accelerate research decisions.

All concluded projects and facilities notebooks are archived in Axxam Archive since 2012.

>150 clients  
>200 projects/year



## INTERNAL AUDIT

Since Axxam is not required to have regulatory certification to perform its experimental activities, the only possible verification occurs with a yearly internal audit by QAU.

At the end of an audit, QAU provides documentation through an audit report about all the findings and any problems that emerged during the inspection, and the recommended measures to improve compliance with company procedures. QAU analyzes the problems/non-compliances detected, evaluating which are the most critical ones.

The audit must be conducted with the aim of finding any non-compliance and, at the same time, raising people awareness of quality policy and stimulating all the inspected functions to activate any possible preventive and corrective actions in the event of non-compliance.

Since 2008	
Facility Audit	16
Audit Reports	253

## LOGBOOKS & EQUIPMENT MAINTENANCE

Each equipment in Axxam (except small instruments, vortex for example) has an Instrument Manager. The instrumentation distributed on different floors has an instrument manager in the group/unit to which the instrument belongs, who is also responsible for training, and a single contact person who is responsible for interfacing with the specialized maintenance technicians. All the documentation issued by specialized technicians in case of ordinary and extraordinary maintenance is also added to Logbooks.

LOGBOOKS	531
Laboratories (4 floors)	30
Equipment typologies	36
Screening Stations	5
Reader instruments	23
Liquid handling	48
Biological hoods	47
Incubators	78

## CONCLUSIONS

The quality system implemented over the years by Axxam, similar to GLP, is a commitment of the Management and it is achieved by engagement and team effort of all employees and by organizational structure of the facility. To this end with a view to continuous improvement, Axxam has undertaken a path that will lead to ISO 9001 and 27001 certifications by an Integrated Management System.

