

## Quality Assurance of Intermediate Qualifications in the Pharmaceutical Industry

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### Abstract

The research collected in the thesis "Professional qualifications of the pharmaceutical industry within the framework of the OLGSE" responds to the need to verify the relevance, quality and effectiveness of the titles of Technician in Manufacturing Operations of Pharmaceutical Products, (TOFPF), in the secondary level and of Superior Technician in Manufacture of Pharmaceutical and Related Products (TSFPA), in higher education. Both are created in 1993, to respond to European Directives and Spanish legislation, since 1991, on Rules of Good Manufacturing Practices, GMP, for human use, veterinary and cosmetics, which requires that manufacturers have sufficient competent personnel, with the adequate qualifications in all its manufacturing facilities to achieve the goal of pharmaceutical quality assurance.

The article includes the evaluation of the quality of the TSFPA qualification from its identification and design mechanisms (1991-1994), as well as the results and effects of its implementation and development (1995-2015), and even its revision (2004-2017). and its impact by providing qualitative and quantitative empirical evidence, according to the reference indicators proposed by the Recommendation on the establishment of a European Quality Assurance Reference Framework for Vocational Education and Training.

**Keywords:**

Qualification, vocational education and training, quality, evaluation, pharmaceutical industry

## Garantía de Calidad de Cualificaciones Intermedias de la Industria Farmacéutica

### Resumen

La investigación recogida en la Tesis "Cualificaciones profesionales de la industria farmacéutica en el marco de la OLGSE" responde a la necesidad de comprobar la pertinencia, calidad y efectividad de los títulos de Técnico en Operaciones de Fabricación de Productos Farmacéuticos, (TOFPF), en el nivel secundario y de Técnico Superior en Fabricación de Productos Farmacéuticos y Afines (TSFPA), en la educación superior. Ambos se crean en 1993, para responder a Directivas europeas y legislación española, desde 1991, sobre Normas de Correcta Fabricación de medicamentos, NCF, de uso humano, veterinario y de cosméticos, que exige que los fabricantes dispongan de suficiente personal competente, con las cualificaciones adecuadas en todas sus instalaciones de fabricación para alcanzar el objetivo de garantía de la calidad farmacéutica.

El artículo recoge la evaluación de la calidad del título TSFPA desde sus mecanismos de identificación y diseño (1991-1994), así como de los resultados y efectos de su implantación y desarrollo (1995-2015), e incluso su revisión (2004-2017) y su impacto aportando evidencias empíricas cualitativas y cuantitativas, de acuerdo a los indicadores de referencia propuestos por la Recomendación sobre el establecimiento de un Marco de Referencia Europeo de Garantía de la Calidad en la FP.

**Palabras clave:**

Cualificación, formación profesional, calidad, evaluación, industria farmacéutica

## Garantia de Qualidade de Qualificações Intermediárias da Indústria Farmacéutica

### Resumo

A pesquisa coletada na Tese “Qualificações profissionais da indústria farmacéutica no âmbito da LOGSE” responde à necessidade de comprovar a pertinência, qualidade e efetividade dos títulos de Técnico em Operações de Fabricação de Produtos Farmacêuticos, (TOFPF), no nível secundário e de Técnico Superior em Fabricação de Produtos Farmacêuticos e Afins (TSFPA), no ensino superior. Ambos foram criados no ano 1993 para responder às Diretivas europeias e a legislação espanhola, desde 1991, sobre Normas de Correta Fabricação de medicamentos, NCF, de uso humano, veterinário e de cosméticos, que exige que os fabricantes disponham de suficiente pessoal competente, com qualificações adequadas em todas as instalações de fabricação para atingir o objetivo de garantia da qualidade farmacéutica. O artigo reúne a avaliação da qualidade do título TSFPA desde seus mecanismos de identificação e criação (1991-1994), assim como dos resultados e efeitos de sua implantação e desenvolvimento (1995-2015), e inclusive sua revisão (2004-2017) e seu impacto, contribuindo com evidências empíricas qualitativas e quantitativas, de acordo com os indicadores de referência propostos pela Recomendação sobre o estabelecimento de um Quadro de Referência Europeu de Garantia da Qualidade na FP.

**Palavras-chave:**

qualificação, formação profissional, qualidade profissional, qualidade, avaliação, indústria farmacéutica.

### Introduction

Among the specific challenges for Europe’s higher education sector, we can find: “[...] equipping students with better knowledge, skills and competences, while addressing skills mismatches and skills shortages in certain occupational fields. (Council of the European Union [CE], 2017, p. C429/3)

The education level is often used as an indicator for human capital and competences among the population (Instituto Nacional de Evaluación Educativa [INEE], 2017), which is measured as the percentage of people who have reached certain level thus obtaining a formal qualification. In Spain, there was no previous data nor formal degrees that followed the European Directive 91/365/CEE (CE, 1991), which sets principles and directives for the Rules of Good Manufacturing Practices (GMP) for medicines in order to maintain high standards of Quality Assurance in the development, manufacturing, and control of medicines. This assurance requires manufacturers to have enough qualified, competent staff to achieve the pharmaceutical quality system’s goal. It also demands that staff receive initial and continuous education

and training about quality assurance and GMP, as well as its application to the different production operations.

This need arises during the reflection process about the educational system and society in Spain, which developed into a new model of vocational training, established in the Organic Law 1/1990 on the General Organization of Education System (OLGSE, 1990), in the context of the future National Qualifications System, first objective of the First National Program of Vocational Training in 1993. The system demands that employability should be the main goal of vocational training (VT), which requires all students to obtain a valid qualification after completing a training course in order to work with responsibility and autonomy. “Specific vocational training will facilitate the entrance of young adults into the labor market, will contribute to citizens’ lifelong learning, and will address the qualification needs of the productive system” (OLGSE, 1990, p. 28933).

### Competency-Based Training

The implementation of competency-based training in Spain, as well as its development in vocational training, raised awareness of the need

for qualified professionals within the Spanish pharmaceutical field, who can adapt to technological and organizational innovations. Due to its relationship with health, the pharmaceutical industry has high qualification levels and the field is dominated by women. Laboratories have to establish and maintain a quality assurance system, and a “qualified person” is responsible for the manufacturing. Generally speaking, this person has a degree in Pharmacy or Chemistry. Even though this person is crucial for the industry, it is not subject of the research; instead, the investigation focuses on manufacturing and preparation operators, as well as their line managers or supervisors, since we have identified a training gap here.

Within the framework of the vocational training reform, and the Chemistry professional family, the author, together with technology and training experts, led the curriculum design based on a sectorial study and according to a methodology, which developed, in 1993, to the creation of the title of Technician in Manufacturing Operations of Pharmaceutical Products (Técnico en Operaciones de Fabricación de Productos Farmacéuticos - TOFPF) (included in upper secondary education) and Higher Technician in Manufacture of Pharmaceutical and Related Products (Técnico Superior en Fabricación de Productos Farmacéuticos y Afines - TSFPFA) (higher education, non-university level).

The study pointed out that the pharmaceutical field in Europe, and Spain, is a leader in R+D, productivity, exports and employment. In addition, the field offers many job positions that require high qualifications, and significantly contributes to the achievement of economic, social, and public health objectives. Some countries, such as France, England, Germany, or Italy, which are leaders in drug manufacture as well, already had structured qualifications for the field, at both university and technical levels. Lack of official qualifications, in the area of technical work for pharmaceutical products manufacturing, made it difficult to train the human capital needed to deal with normative regulations, technological innovation and enterprise internationalization.

### **The qualifications system**

Once competency-based training was implemented in middle and higher vocational training by

the end of the 1990s, besides other challenges, the articulation between the different learning methods was still pending, mainly with the training of employed and unemployed workers, who were managed by the labor administration. Moreover, it was necessary to implement procedures to recognize formal and non-formal learning, and improve the quality of available training programs, as well as their image and social vision. Therefore, the Government agreed on creating for employers and employees a second National Program of Vocational Training in 1998, aimed at designing the Qualifications System, with the support of the National Institute of Qualifications (Instituto Nacional de las Cualificaciones - INCUAL).

INCUAL is an independent technical instrument created by Royal Decree 375/1999 as a technical support body of the General Council of Vocational Training (Consejo General de Formación Profesional - CGFP), in order to determine the qualifications that made up the National Catalogue of Professional Qualifications (Catálogo Nacional de Cualificaciones Profesionales - CNCP). Because of this collaboration, Organic Law 5/2002 of June 19 on Qualifications and Vocational Training (OLQVT) was approved, which created the National System of Qualifications and Vocational Training whose main instrument is the CNCP. A qualifications system is made up of:

Qualifications systems include all aspects of a country's activity that result in the recognition of learning. These systems include the means of developing and operationalising national or regional policy on qualifications, institutional arrangements, quality assurance processes, assessment and awarding processes, skills recognition and other mechanisms that link education and training to the labour market and civil society. Qualifications systems may be more or less integrated and coherent. One feature of a qualifications system may be an explicit framework of qualifications. (OECD, 2008, p. 27)

The global inventory of regional and national frameworks for qualifications (Cedefop, 2017) systematizes up to 154 countries that are developing national qualifications systems (NQS) as part of their qualifications systems. Four common ele-

ments in all the systems were identified: legislation, participation of stakeholders, institutions, and quality assurance.

Article 7 of OLQVT (Organic Law 5/2002) defines Occupational qualification: The set of occupational skills with meaning for the occupation that can be acquired through training in modules or other types of training and through on-the-job experience. The qualifications are accredited through titles of the educational system and occupational certificates of the labor administration. The transposition of the European Directive regarding the recognition of professional qualifications (Royal Decree 581/2017) defines professional qualification as the “capacity to access to a certain profession, or its practice, which is officially documented by a training degree, a certificate of competence as it is defined in Article 19.1.a), formal work experience, or the combination of some of these” (p. 48163). In Appendix 1 of the European Qualifications Framework for lifelong learning (CE, 2017), a qualification’ means “a formal outcome of an assessment and validation process which is obtained when a competent body determines that an individual has achieved learning outcomes to given standards” (p. C183/20).

The Catalogue is ordered vertically in five levels of qualification and horizontally in 26 professional families 26 professional families. The 5 levels of qualifications are based on the professional competence required for each productive activity taking into account different criteria like knowledge, skills, initiative, autonomy, responsibility and complexity, among others, which are required for the accomplishment of every activity. The qualification levels are related to Royal Decree 581/2017, Classification of Education (CNED), Classification of Occupations (CNO), and contribution groups. Within the Chemistry professional family, managed by INCUAL, and with the participation of experts of productive organizations and the training field, new professional qualifications of levels 2 and 3 were defined for the pharmaceutical industry in 2005, which made it possible to update the degrees and create occupational certificates.

The National Qualifications System involved normative changes of great impact for the accreditation of professional qualifications of the CNCP

with degrees of the educational system and labor administration’s occupational certificates. The Organic Law 2/2006 of May 3 on Education (OLE) was then approved and later modified by LOMCE in 2013, which allowed for renewal of the degrees established in the framework of OLGSE. The regulation of vocational training for employment was also modified, and the Repertory of Occupational Certificates was created, which are directly linked to the CNCP. Furthermore, the regulation of 2009 was established, which recognizes knowledge acquired through work experience and non-formal learning; this is essential for a field in which there was no official qualification or training before 1993.

The degree of Higher Technician is registered in the Spanish Qualifications Framework for Higher Education, MECES, established by Royal Decree 96/2014. This framework has four cycles: the post-secondary, non-university degree of Higher Technician (subject of this research), as well as other degrees, is part of level 1 of MECES. Level 2 is bachelor’s degree, level 3 is master’s degree, and level 4 is PhD. Each level has its own generic descriptors based on learning outcomes and includes an estimated sum of credits.

### Research objective

We want to determine whether the decision of creating these two qualifications (Cedefop, 2015) was right by assessing the usefulness of the degree, as a formal recognition, to find a job or to pursue further studies, outlined by the learning outcomes of people who completed the training program and passed the examinations. In order to do so, this paper reviews the doctoral dissertation about “Professional Qualifications of the Pharmaceutical Industry in the framework of OLGSE” (Arbizu, 2015) between 1990 and 2015, in order to assess the quality, relevance and effectiveness of the first qualifications, through their identification and development mechanisms, as well as their application results.

The relation between training, productivity and wages is often claimed to be real, but showing evidence with data and indicators requires analysis and research of the mechanisms that lead to those effects. In every country (OECD, 2016), substantial changes in the competence needs are cha-

llenging the labor market and training policies. In most countries, a great share of employers complains about not finding workers with the skills needed by their companies. On the other hand, one of the objectives of the 2030 Agenda for Sustainable Development involves ensuring equal access for all women and men to affordable and quality technical, vocational and tertiary education, including university (UN, 2015).

The research **hypothesis** is similar to the outcome described in Section 5, Article 30, of OLGSE, which established the following for specific vocational training: professional qualifications certified with the degrees of Technician in Manufacturing Operations of Pharmaceutical Products (TOFPF) and of Higher Technician in Manufacture of Pharmaceutical and Related Products (TSFPA) facilitate the integration of young adults into active life, contribute to citizens' lifelong learning, and address the qualification demands of the productive system. The **objective** is to assess the quality of professional qualifications certified with TOFPF and TSFPA degrees through their identification and development mechanisms, as well as the results and effects of their application.

## Method

### Design

This research takes the European recommendations and criteria of quality assurance in education and vocational training as a reference, as well as the possibility to obtain accurate data for the quality assessment of the degrees of Technician and Higher Technician, which are the focus of the investigation. Thus, the research design has three aspects:

- a. Adaptation of training to qualification and employment needs in pharmaceutical products manufacturing.
- b. Quality of training and accreditation in the manufacture of pharmaceutical products.
- c. Graduation, employability and education-training transition of graduates in pharmaceutical products manufacturing.

Evaluation (OECD, 2010, p. 21) is "the systematic and objective assessment of an on-going or com-

pleted project, program or policy, its design, implementation and results. The aim is to determine the relevance and fulfillment of objectives, development efficiency, effectiveness, impact and sustainability." This research applies a methodology of program evaluation of both professional qualifications certified with the degrees of TOFPF Technician and TSFPA Higher Technician, which includes a series of indicators used to systematically assess the two degrees of VT.

According to these indicators and other information about the quality of these degrees, both in their origin and implementation, the results can provide criteria for the improvement of the qualifications of the pharmaceutical field technical staff, and the promotion of the evaluation culture as an instrument of ongoing improvement and transparency that improves the training operation.

### Participants

**Sample of students and graduates:** it is a census sample made up by the universe of enrolled students, graduates and degree holders in Spain. In intermediate training cycles, the total sample is 1788 enrollments and 559 Technicians in Manufacturing Operations of Pharmaceutical Products. In advanced training cycles, the total sample is 2379 enrollments and 975 Higher Technicians in Manufacture of Pharmaceutical and Related Products.

**Sample of employability surveys taken by degree holders:** We have covered the period between 2005/2006 and 2006/2009 only in the Autonomous Region of Catalonia, and the sample is 378 surveys taken by 105 TOFPF and 279 TSFPFA degree holders.

**Sample of pharmaceutical industry workers in the accreditation process of competences acquired through work experience:** Data of the Autonomous Region of Catalonia within the 2007/08 and 2008/09 period was considered, in a sample of 73 and 124 workers who underwent the accreditation process at the middle and upper grade levels, respectively.

### Instruments

Because of the long research process between 1990 and 2014, we have used different techniques and instruments, which are part of the qualifications life span, for the evaluation of vocational

training in the pharmaceutical industry. These techniques and instruments must be considered in accordance with some criteria and indicators to be analyzed. We have combined primary and secondary sources, as well as their analysis: normative analysis, statistics, semi-structured interview, direct observation, surveys in training centers, surveys in enterprises and pharmaceutical organizations, and case study.

## Process

### Cycle of quality assurance in vocational training

The development of the vocational training reform of OLGSE introduced deep changes, both in the system origin and order, which suggested the implementation of a system evaluation with a forward-looking approach, in order to correct the existing deficits and design future appropriate corrective measures. The truth is that Spain has not implemented any vocational training evaluation so far, not even a sectorial evaluation focused on certain degrees. This research aims at determining whether the employment-qualification-training relation in the pharmaceutical manufacturing field improves because after the implementation of training related to the two professional qualifications that are subject of the investigation.

However, some Autonomous Regions have established an institutional plan of vocational training quality assurance. Thus, Catalonia has developed three evaluation initiatives that provide elements of interest: Evaluation of Regulated Vocational Training, relating to the period 2001-2008, by the Higher Council for the Evaluation of the Educational System (Generalitat Cataluña, 2012); the Annual Study of Employability of Vocational Training, promoted by the Department of Education with the Catalonia Council of Chambers since 2005, and the Project of Quality and Continuous Improvement promoted by the Department of Education and Universities since the 1998-1999 period through experiences for management improvement in secondary education institutes that provide specific vocational training.

In order to assess the TOFPF and TSFPA programs, we have used the Recommendation of the European Parliament and of the Council of 18 June

2009 on the establishment of a European Quality Assurance Reference Framework for Vocational Education and Training (EQAVET) (CE, 2009). On the other hand, we have considered the principles of quality assurance of qualifications that are part of the national qualifications frameworks or systems related to the European Qualifications Framework stated in Appendix IV of the Recommendation (CE, 2017). Moreover, we have also considered the Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG) (ANECA, 2015), agreed by the Ministers of Education of the countries involved in the Bologna Process.

The Framework has a four-phase cycle of quality assurance and improvement:

**Planning:** It involved identifying the need for qualifications in the manufacturing industry of pharmaceutical and related products through a sectorial study and the analysis of international benchmarks of neighboring countries that already had qualifications for the pharmaceutical industry. Besides, professional profiles and training were established as learning outcomes with evaluation criteria, according to the methodology of degrees in the Chemistry professional family.

**Implementation:** It is the execution of training cycles by using available resources, training centers, faculty, and enterprises for workplace training, in order to achieve the learning outcomes defined as abilities and competences.

**Evaluation:** It is the analysis of results and effects of the intervention during the implementation, in order to learn from this experience. Evaluation can be understood as a phase in the vocational qualification cycle and as an activity that has an influence on others.

**Feedback:** It is the development of change procedures in order to update the targeted vocational qualifications for the pharmaceutical industry.

Each of these phases is based on quality criteria and indicative descriptors to be applied in the system and vocational training centers, as well as in the qualification levels. The quality assurance cycle provides a systemic approach of feedback regarding quality by combining internal and external assessment, evaluation and other improvement processes, in accordance with qualitative and quantitative analyses.

The report on the progress in quality assurance in VT within the EU (CE, 2014) after implementing the Recommendation of EQAVET states that it has contributed to the promotion of the quality culture in vocational education and training (VET) and its practical application, but it still has to improve its application and connection with ESG and the European Qualifications Framework.

The Conclusions of the Council about a renewed EU agenda for higher education (CE, 2017) claim that at least 40% of the population between 30 and 34 years old should complete higher education (or equivalent) by 2020 in order to move towards the main objective of Europe 2020, yet it is necessary to ensure high-quality and relevant higher education that will allow graduates to succeed in their personal and professional life. Quality assurance is important when dealing with challenges such as improving its adequacy to the labor market, improving employability of young adults, increasing its appeal, and facilitating mutual recognition of knowledge acquired in different countries through different types of learning. This would achieve greater mobility and better response to economic and social challenges. The New Skills Agenda for Europe (CE, 2016) encourages us to work together in order to strengthen human capital, employability, and competitiveness.

### **Longitudinal evaluation: 25 years of qualifications**

This is a longitudinal research that covers the origin of degrees, their evaluation and implementation, which is a 25-year cycle within the 1990-2015 period. It is important to remember that the author was responsible for the creation and design of degrees in the 1990-1993 period, and she was the Director of the National Qualifications Institute since its establishment until the end of 2008 (Arbizu, 2012). This research focuses on how these two degrees have been implemented in the autonomous regions in different training periods of intermediate (CFGM) and advanced (CFGs) training cycles.

As a matter of fact, the evaluative research starts with the implementation in the 1999/2000 period in different centers. Analyzing the process through which the TOFPF and TSFPFA degrees were implemented will allow us to come up with

conclusions about the relationship between the educational administration and pharmaceutical laboratories. This relation will be essential for training qualified professionals (recalling the module of workplace training) and recognizing the qualifications of workers that have acquired their vocational skills through work experience.

The quantitative study of the results of its application in young adults, workers, and the manufacturing industry of pharmaceutical and related products covers the period between 1999/2000 and 2014/15, when available training was still active in Andalusia, Asturias, and Catalonia. Therefore, we have considered 25 years since its conceptualization, and 16 academic years of application of these two degrees, so this long period is enough to assess the relevance, quality and impact of those degrees.

### **Evaluation of results and effects. Evaluation criteria.**

The elements assessed according to the terminology of system analysis are:

- Inputs: Resources, students, faculty, equipment, etc.
- Throughputs: The development process of training cycles.
- Outputs: The final product pursued by the training activity, which is reflected in the acquisition of knowledge, skills and abilities.
- Outcomes: The effects caused in participants and their work performance, as well as the whole organization, after training.

The evaluation methodology is focused on the results (outputs) and the effects (outcomes) after a period of time since the end of training cycles, in order to verify how permanent and consistent the changes in people, enterprises and society were.

This research pays attention to impact evaluation (Billorou et. al, 2011), which determines whether the project had an impact in its environment in terms of economic, technical, sociocultural, institutional and environmental factors (OECD, 2010). It is also understood as a process aimed at measuring the results (changes and causes) of formative actions that were developed in the socio-professional setting, which emerged from the same actions over time (Ferrández Lafuente,

2006, p. 20). This is why this research has tried to measure the results after some time since the beginning of the implementation.

After considering the definitions of impact evaluation, it is necessary to know what changes were made after the implementation and development of these vocational training programs (in their beneficiaries), as well as the variety of impacts that the intervention may have (such as economic or social impacts), which can be expected (defined among the activity objectives to be assessed) or not.

## Results

The results obtained are related to the research objectives.

### **Adjustment of the TOFPF and TSPFA degrees to the qualification needs of the manufacturing industry of pharmaceutical and related products**

The pharmaceutical industry in Europe is the high-technology field with the greater value added per person employed, which is significantly higher than the average value for manufacturing and high-technology industries (European Federation of Pharmaceutical Industries and Associations [EFPIA], 2014). The pharmaceutical sector represents a great contribution to the trade balance in areas of great intensity of high-technology and R+D; it also offers job positions of high qualification and significantly contributes to the achievement of economic, social, and public health goals. In Spain, the pharmaceutical industry is a leader in R+D, productivity, exports, and employment. The study has confirmed that within the 1995-2013 period in the field of pharmaceutical products manufacturing (Minetur, 2015), the production index increased from EUR 6,104.035 to EUR 12,833.479, and employment decreased slightly from 39.242 to 36.992. Productivity (VA/employed) increased from 56.4 to 112.9, hence the unit labor cost has decreased from 67.9% to 51.3%.

The general competence of the Technician in Manufacturing Operations of Pharmaceutical Products (TOFPF) is "to perform all process and

control operations of different stages of pharmaceutical and related products manufacturing, monitoring the operation and start-stop processes of the equipment in the established safety, quality, and environmental conditions, being responsible for the equipment's first-level maintenance" (Royal Decree 816/1993, p. 24708). In the Higher Technician training cycle, the competence is "to organize and participate in a production line or team, monitoring the pharmaceutical process and its quality, complying with the Rules of Good Manufacturing Practices, and supervising the compliance of safety and environmental regulations" (Royal Decree 810/1993, p. 23020). There is a modular training linked to this profile, which has a stage of workplace training to address the needs for human capital qualifications, in accordance with the curriculum reforms in Europe (Cedefop, 2012).

The degrees are related to the classification of workers from the 17th General Collective Agreement of the Chemical Industry (Dirección General de Empleo, 2013). The Higher Technician degree corresponds to group 5, which includes performing the functions of integrating, coordinating and supervising the execution of many homogeneous tasks, while being responsible for organizing the work of many employees in a functional manufacturing or packing unit by supervising the facilities and processes. The Technician degree corresponds to level 3 and 4. It is important to analyze this relation as it is the base of wages and work conditions. It is a sector free of labor conflicts, with job stability and fair wages.

It created around 200,000 jobs in Spain in 2017, and over 37,000 were direct positions. It is a quality sector, since 96% of workers in the pharmaceutical industry have open-ended contracts and equal conditions, as almost 50% of them are women.

### **Implementation of training cycles in Autonomous Regions in regard to the industrial environment**

The freedom that OLGSE gives to the Autonomous Regions to complete their own curriculum based on minimum requirements has led to the development of four different training cycles, in the case of the Technician degree, in Asturias, Andalusia, Navarra, and Catalonia. The implementation pro-



cess of the training cycles for drug manufacturing is promoted, mainly through agreements, by surrounding pharmaceutical enterprises, especially in Catalonia.

Even though there are good educational statistics in the Government, yet no quality assurance system, some Regions have established an institutional plan of vocational training quality evaluation. Catalonia has developed evaluation initiatives that have provided essential elements for the investigation. On the one hand, there is the evaluation of Regulated Vocational Training, covering the 2001-2008 period, by the Superior Council of Evaluation of the Educational System, according to the Evaluation Plan of the Department of Education and 2008 guidelines (Gen Cat, 2008). This evaluation does not cover the level of concrete training cycles. Furthermore, there is the project of Quality and Continuous Improvement promoted by the Department of Education and Universities since 1998-1999, which improves management in secondary education institutes that provide specific vocational training.

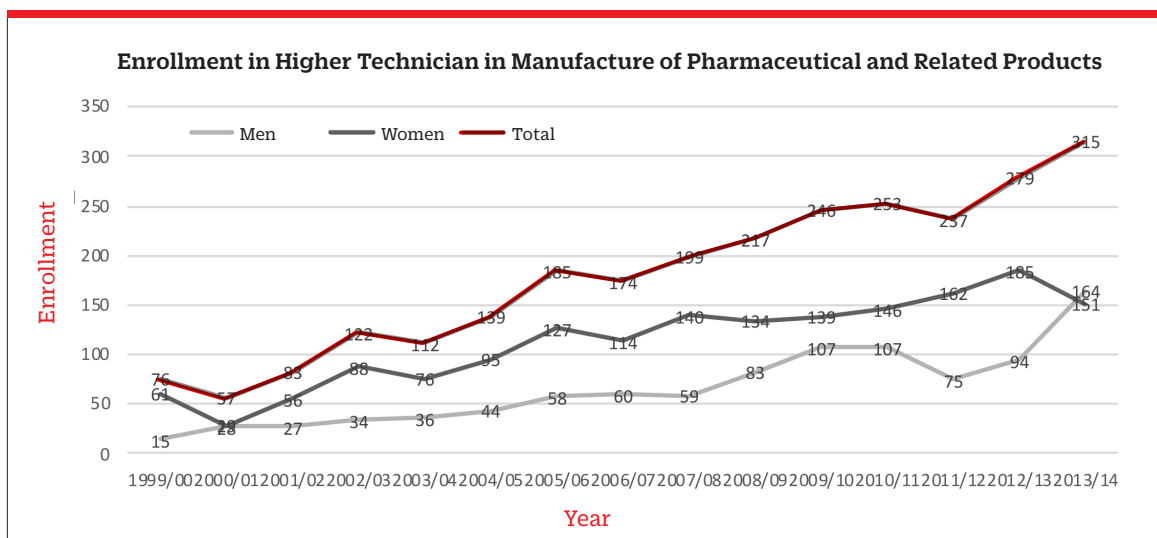
The EQAVET Indicator No. 1, Relevance of quality assurance systems for VET providers, was applied. In the period between 1999/2000 and 2014/2015, training cycles were developed in 10 centers of 4 autonomous regions: the intermediate training cycle of TOFPF was carried out in a center in Andalusia (Almeria), one in Asturias, one

in Navarra (Pamplona), which is not active anymore, and five in Catalonia (Barcelona). The advanced training cycle of TSFPFA was developed in six centers of Catalonia, and all of them were located in Barcelona. All educational centers in Catalonia are certified with quality assurance systems, either by ISO 9001 or EFQM.

The EQAVET Indicator No. 2, Investment in training of teachers and trainers, is especially important for the quality assurance of qualifications: share of teachers and trainers participating in further training, and amount of funds invested. Since there were new lessons, it was essential to train the existing faculty, especially chemists. The surveys and interviews of this research show that there was both initial and ongoing training, as well as placement in enterprises, but not in a systemic, assessed way.

**Student participation in TOFPF and TSFPFA training cycles**

The EQAVET Indicator No. 3, Participation rate in VET programs, and Indicator No. 8, Prevalence of vulnerable groups according to gender, were used. Student participation in the intermediate cycles of TOFPF in the period between 1999/00 and 2013/14 shows 1,997 enrollments. In the case of the advanced cycles of TSFPFA, there were 2,694 enrollments with a positive, slow and ongoing growth rate.



**Figure 1.** Students registered in the TSFPFA advanced training cycle, from 1999/00 to 2013/14

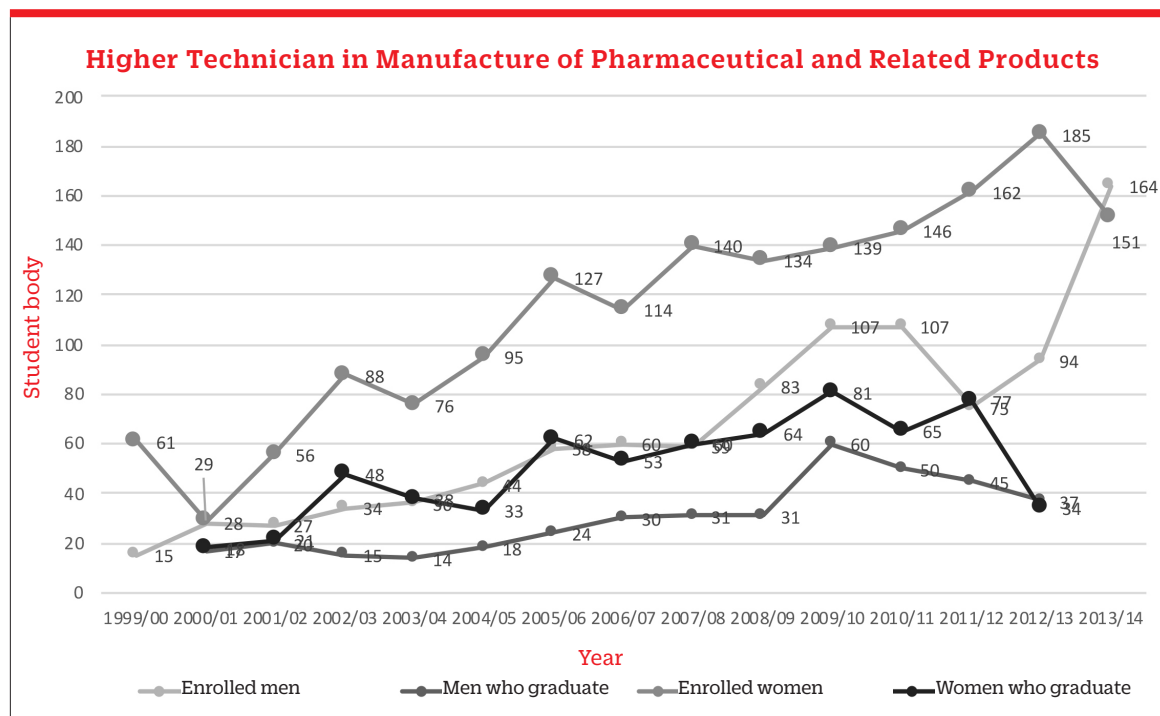


Figure 2. Enrolled students that completed the TSFPFA by gender. From 1999/00 to 2013/14

In both cases, the number of women is 63% higher than men, yet the difference was even greater during the first years of development of the cycles because of the agreements between the Department of Education, enterprises and accreditation centers for female workers. The number of men increased with the economic crisis by coincidence. According to geographical distribution, Catalonia is the leader with more than 70% of enrollments in the intermediate cycle and 100% in the advanced cycle.

### Improving access to training in Human Resources Management

The structure of the professional profiles of each degree, organized in units of competence, has made it possible to certify vocational skills acquired by workers of the manufacturing industry of pharmaceutical and related products through their work experience and ongoing training. The Indicator No. 10, Schemes used to promote better access to VET, was applied. The evidence of access to training for people who do not have academic requirements promote the integration of disadvantaged groups, especially women and

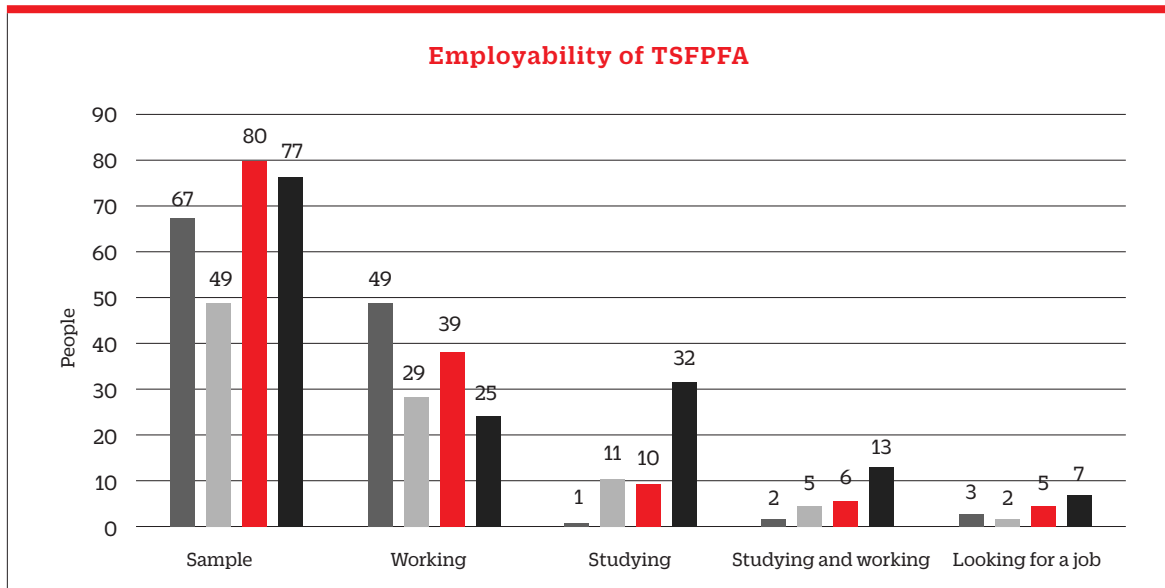
older workers that joined the field when there was no training.

The combination of competence evaluation and accreditation procedures with evidence of access to training for people with no academic requirements, as well as available modular training, has increased the qualification level of human resources in the pharmaceutical industry.

The availability of specific degrees in this industry has benefited enterprises such as Grifols, which have dealt with internationalization processes in United States, where manufacturing staff needs to be certified. The degrees have increased the qualification level and are required for the staff selection process in some enterprises like Novartis. Many TOFPF graduates prepare entrance examinations to access advanced training, and not many TSFPFA graduates go to college.

### Graduates of Technician and Higher Technician in Manufacture of Pharmaceutical and Related Products

This is related to the Indicator No. 4, Completion rate in VET programs: Number of persons



**Figure 3.** Employability and educational progression of Higher Technician degree holders, periods 2005/2006, 2006/2007, 2007/2008, and 2008/2009

having successfully completed/abandoned VET programs. A person obtains a degree after passing every professional module that made up the Formative Cycle, when the student gets 5 or more points, and is accepted in the module of Workplace Training. If a person completes or graduates from the program, he or she gets promoted as well; in the case of student-workers it is done through validation, accreditation and recognition of professional competences acquired by means of work experience or non-formal ways, and through exemption from the FCT module.

In the period between 2000/01 and 2013/2014, 630 TOPFP Technicians got a degree and 64% of them were women. In the case of Higher Technicians, there were 1,046 TSFPFA and 62% were women. All degree holders are qualified staff according to the Rules of Good Manufacturing Practices, and this allows for the update of staff without professional qualifications, which is incompatible with the ongoing process of technological innovation and internationalization.

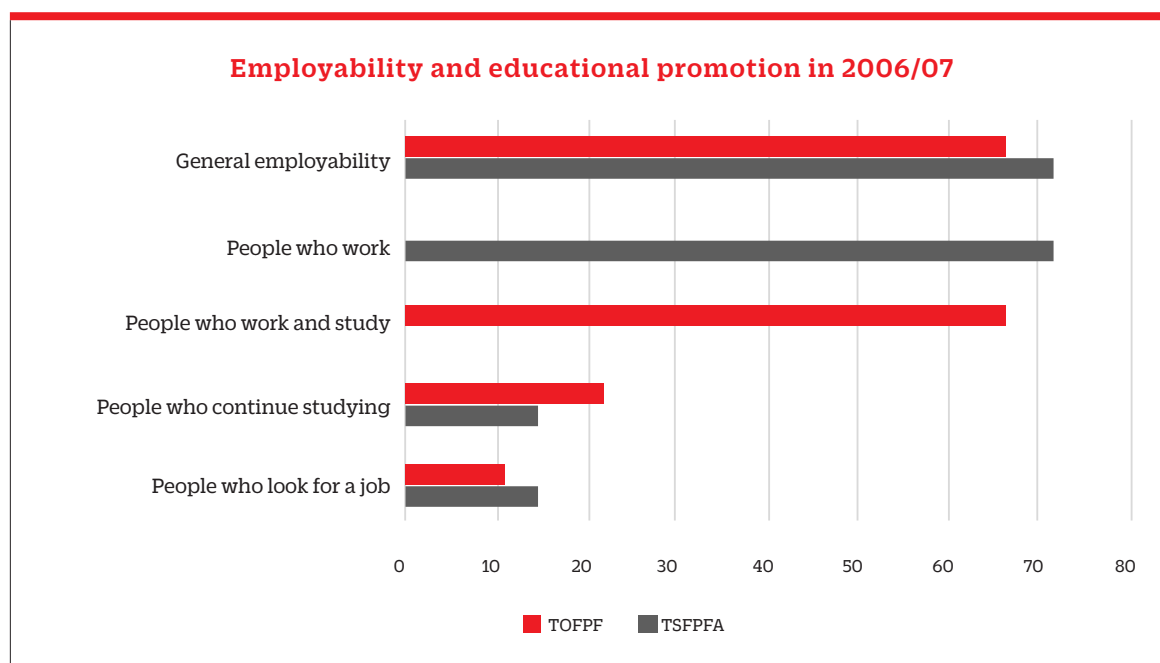
The completion results of training cycles regarding the students enrolled show 35% in intermediate training and 43.96% in advanced training, in which the pharmaceutical and cosmetics industry has a great impact, as many female workers balance their work life and training because of

the school-enterprise collaboration. This requires women to spend more time trying to obtain their degree, thus the degree holders/enrolled students ratio is low.

**Employability and educational transition of degree holders**

The Indicator No. 5, Placement rate in VET programs, and the Indicator No. 7, Unemployment rate, were both applied. We have used the results of the Annual Study of Employability of Vocational Training, conducted by the Department of Education (Generalitat Catalunya, 2015) and the Catalonia Council of Chambers, about the TOFPF and TSFPFA graduates from 2006 to 2012/13. These results show, in general and with periodical changes because of the crisis, a positive rate of employability and great adequacy of education to work, which is always higher in the superior technician degree. The workplace training module, inspired by the German dual system of vocational training, was a big challenge and one of the success pillars for employability of degree holders.

Superior technicians that continue studying, mainly in college, are few compared to the TOFPF technicians that pursue further education by preparing for the entrance examination for



**Figure 4.** *Employability and educational promotion of students in Narcis Monturiol secondary school*

the advanced training cycle. A few graduates are unemployed in the moment of the survey, after six months of completion. Many have temporary contracts, and most of them have full-time jobs.

Wage rates are divided among people who earn more than EUR 1,500, those who earn between EUR 1,200 and 1,500, and those who earn between EUR 900 and 1,000 (10:40:40). Employability rates are higher than the Catalonia mean, and job quality regarding adequacy of education and work is also better, and TSFPFA is among the top five popular degrees.

Employability six months after obtaining the degree is high and positive in Catalonia. Workplace training contributes to it. TSFPFA degree holders who go to college are able to validate up to 33 credits. Employment is related to majors and job positions: specialty and conditioning operator is common for TOFPF, whereas line manager, team manager, and manufacturing or conditioning manager are more common for TSFPFA.

This was complemented with a specific study in Narcis Monturiol secondary school, in which Indicator No. 6, Utilization of acquired skills at the workplace, was applied.

This secondary school has seven training cycles

of Chemistry, including two Pharmacy cycles. The results were positive, especially for the Higher Technician degree because of its high employability and quality, in the studies conducted by the center regarding quality management of students taking workplace training and graduates.

### Review of professional qualifications

The research concludes with the review of the TOFPF and TSFPFA degrees of 1993 in the framework of OLGSE in 1990. This result covers the Indicator No. 9, Mechanisms to identify training needs in the labor market. The implementation of the System of Qualifications led to the elaboration of the National Catalogue of Professional Qualifications designed by technology and training experts of the sector and validated by sectorial organizations. From 2005 to 2011, five new professional qualifications were researched, designed and established. Two of them correspond to level 2 for the Technician degree: Production of pharmaceutical and related products, and Conditioning operations of pharmaceutical and related products. The other three professional qualifications correspond to level 3 for the Higher Technician degree: Organization and monitoring of pharmaceutical

and related products manufacturing, Organization and monitoring of processes, and Execution of biotechnological services.

These new professional qualifications are the foundations of new available training, which is integrated and articulated, certified by degrees of the educational system and certificates of professionalism. In the context of the updated Law of Employment and OLQVT of 2002, in the 2011-2013 period, five Occupational Certificates were approved and published with each new professional qualification. This type of training is oriented to employed and unemployed workers, and officially certifies the corresponding professional qualifications within the territory.

Based on Organic Law 2/2006 of Education (LOE, 2006), modified by Organic Law 8/2013 (LOMCE, 2013) for the improvement of education quality, the educational administration has developed and implemented the new degree of Higher Technician in Manufacture of Pharmaceutical, Biotechnological and Related Products through Royal Decree 832/2014 in reference to the three professional qualifications of level 3.

The new Higher Technician degree has been replacing TSFPFA and extending its outreach, since it has been implemented in four secondary schools in Andalusia, Catalonia, and Basque Country. The TSFPFA degree has the same professional and academic effects compared to the new Higher Technician degree. Available training is therefore sustainable in the advanced cycle, which allows for training young adults and workers in the manufacturing of pharmaceutical, biotechnological and related products, even though traceability between competence units and professional modules is not guaranteed.

The TOFPF intermediate training cycle in the 2017/2018 period is still offered in five secondary education institutes of Catalonia, according to the Register of educational centers, though Royal Decree 832/2014 expected it to disappear since 2016. So far, no Technician degree that could replace the TOFPF (which dominates the field) has been approved.

A fundamental outcome is that the five CNCP qualifications allow the recognition of competences acquired through work experience and non-formal training since the approval of Royal

Decree 1224/2009, which facilitates the obtention of degrees.

## Discussion

Overall this research has had the expected outcomes that are related to the guidelines of OLGSE, 1990, and the National Qualifications System created by Law 5/2002, because the results about the two professional qualifications certified as Technician in Operations and Higher Technician in Manufacture of Pharmaceutical and Related Products show that these training cycles facilitate the integration of young adults into working life, contribute to citizens' ongoing training, and address the qualification demands of the productive system.

Quality assurance systems promote the generation of trust in qualifications. Statements that claim it is necessary to have relevant qualifications of good quality with positive results are very common in the scientific literature. However, there are few research studies that could prove it, as it is necessary to have long periods of time in order to observe and measure the results of education and training in the labor market, as well as educational progression and mobility.

The main conclusions of this study are summarized here:

1. This research covers the quality cycle of the two professional degrees, since it starts with their design and planning (1990-1993) as competency-based training in the framework of OLGSE. They are the first vocational training degrees for the pharmaceutical industry in Spain, and the study assesses the results according to reference indicators stated in the Recommendation on the European Quality Assurance Reference Framework (EQAVET).
2. The pharmaceutical industry is the high-technology field with greater value added per employed person with constant increase during the research period. This proves that it was right to train qualified personnel in the technical field, since this had already existed in better developed countries at the beginning of the investi-

- gation. The analyzed degrees comply with GMP.
3. The vocational training model focused on competences adopted by OLGSE, the methodology used in collaboration with renowned experts of the field, and the use of international benchmarks are key elements that contribute to the existence and relevance of the Technician and Higher Technician degrees, established in 1993, even in 2015, in spite of the technological and organizational innovations of the sector. The professional profiles, structured by competences, match the pharmaceutical field demands, and their training contributes to the improvement of productivity of people. This model is similar in other countries and makes qualifications transparent to the public.
  4. Available TOFPF and TSFPFA training cycles are relevant and efficient regarding knowledge and competence demands of the Rules of Good Manufacturing Practices in the pharmaceutical industry, especially in the technical production work segment.
  5. The structure of professional profiles according to competence units has made it possible to certify professional competences acquired by pharmaceutical products manufacturing workers, either through work experience or other types of training. This accreditation facilitates the obtention of the TOFPF or TSFPFA degrees.
  6. The TOFPF and TSFPFA degrees improve human resources management, since they certify vocational qualifications for operators and supervisors of pharmaceutical products manufacturing. They also provide jobs for degree holders, and they are required to get a position nowadays; besides, they allow for progress in education and ongoing training, as well as promotion and mobility of degree holders.
  7. The school-business collaboration is extremely useful for higher qualification standards through the vocational module of Workplace training, which is a high-quality employability mechanism.
  8. The implementation of the Qualifications System, which combines training centers, workplace training, entrance exams and the accreditation of acquired competences in pharmaceutical enterprises, is a useful learning strategy throughout life. This has benefited international competitiveness by providing success stories such as the agreement between Grifols company and La Románica secondary school.
  9. The implementation of the TOFPF and TSFPFA training cycles is predominant in Catalonia because of the importance of the pharmaceutical sector there. The development of mechanisms to evaluate these training has made it possible to state that employability results of degree holders in pharmaceutical enterprises are high and solid. Furthermore, there is a positive educational progression of degree holders through entrance examinations, especially from Technician to Higher Technician,
  10. This is a sustainable training offer, since the TOFPF and TSFPFA degrees of 1993, created in the framework of OLQVT 2002, have been updated with five Occupational Certificates and with the Higher Technician in Manufacture of Pharmaceutical, Biotechnological and Related Products degree. The TOFPF degree is temporarily maintained, which endangers the formal training of pharmaceutical products manufacturing and conditioning operators.

### Recommendations

This research has had an unexpected effect: we have achieved a model and methodology of systemic, cyclic evaluation of the TOFPF and TSFPFA degrees in the pharmaceutical sector, which can be useful as public authorities have to undertake this essential task about vocational training cycles, especially because they are involved in employment. This way, we will be able to fulfill the commitment of the European Recommendation on Quality Assurance EQAVET and conduct an evaluation of qualifications and training, which will allow us to make deep changes in enterprises, organizations and the labor market, in order to confirm that lifetime investment in training is one of the actions that empower us to successfu-

lly deal with challenges such as globalization and technological innovation in enterprises, organizations, and the labor market.

In a comprehensive way, this research suggests an indicator system based on European recommendations, which would be used to systematically assess the degrees regarding the quality assurance cycle of vocational training. Some of these indicators require statistical information that is not available in the country, and it also requires faculty training, which needs further efforts.

It is advisable to apply the Council Recommendation of 2017 on tracking graduates (CE, 2017b) in the framework of the New Skills Agenda for Europe, in order to improve information and documentation regarding the transition of these graduates into the labor market, so we will be able to take informed decisions about vocational training and majors.

It is necessary that the Ministry of Education adjusts their decisions about the new Higher Technician degrees to the targeted vocational qualifications, according to OLQVT, in order to achieve greater linkages with the available training of the CNCP for workers and improve validation and recognition effects of competence units included in the analyzed professional qualifications. Moreover, according to the results, it is recommended that public authorities that are responsible for qualifications pay attention to strategic sectors with few workers, but with great value added and need for qualified personnel, which is the situation of the pharmaceutical industry.

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