Drug Development and Industrial Pharmacy, 23(4), 351-358 (1997)

RESEARCH PAPER

Editing of a Job Description

Mireia Lázaro-Doltra[1] and Encarna García-Montoya[2,*]

[1]SEMAR-DERMOFARM, Barcelona, Spain
[2]Pharmaceutical Technology Unit, University of Barcelona, Barcelona, Spain

ABSTRACT

The article contains a review of all the regulations (GMP, GLP, and ISO 9000) in which the concept of job description is discussed. Different approaches with regard to the matter under consideration are judged (a comment on the advantages and disadvantages is included) and a standard form is proposed as an example.

INTRODUCTION

The maintenance of written job descriptions recording all the specific duties of personnel is nothing new; however, certain additional difficulties arise when writing them compared to the writing of the remaining procedures of a quality assurance program. The cliché of "leaving things as they are," so deep rooted in the previous manufacturing techniques, could possibly produce good results in the case of the experienced employee who knows all the secrets of the company and is highly recognized by the chief director. But at present nobody would trust this behavior to be right because the present competitive environment asks for dynamic companies, capable of quickly adapting to the changing needs of the market, and above all capable of working always with the proper attitude and strictness, leading to quality.

This is the reason why the person in charge of the quality assurance department usually is concerned about the writing of job descriptions when the rest of the quality programs have already been implemented. The advantage of this approach is that when the implementation process is under way, the personnel are much more receptive towards all the issues related to quality and standardization, and clearly understand that nobody is trying to control their job. Similarly, the writing of job descriptions helps the company to decide if the target is to create a total quality assurance system and, consequently, to go further on with aspects such as personnel certification, development of quality loops, and so on.

A company should guarantee its potential consumers that it can achieve the standard of quality intended in its

*To whom correspondence should be addressed at the Pharmaceutical Technology Unit, Pharmacy Department, University of Barcelona, Joan XXIII s/n, 08028 Barcelona, Spain.

products. To this end, the company should implement its quality policy at three levels:

- *Quality related to the organization*: Organization adapted to the strategic objectives and to the competitive advantages, etc.
- *Quality related to processes*: Identify key processes; document all the operations; establish records in order to evaluate the degree of quality achieved.
- *Quality related to personnel:* Each individual, regardless of position, should receive information, training, and motivation.

REGULATIONS: IS IT COMPULSORY ACCORDING TO THE REGULATIONS TO MAINTAIN CURRENT JOB DESCRIPTIONS?

The chief director (or similar officer) who does not really believe in the quality assurance system being developed in the company, or maybe a technician who intends to avoid trouble in his or her department, usually wonders if there is a legal requirement for implementation of job descriptions. What is, then, the *legal requirement* supposed to mean?

The Good Manufacturing Practice (GMP) items relevant to this subject are slightly contradictory (2):

Chapter 2, Personnel, Principle, reads literally: "individual responsibilities should be clearly understood by the individuals and recorded." Meanwhile point 2.2. refers only to "personnel in responsible situations." This divergence tends to confuse those who are not inclined to implement the quality assurance system. According to GMP regulations, key personnel include the head of production, the head of quality control, and if at least one of these persons is not responsible for the release of products, the authorized person(s) designated for the purpose. This is also specified in the GMP regulations which are the basic responsibilities, both individual and jointly exercised, of key personnel.

As far as the Good Laboratory Practice (GLP) is concerned, the concepts are much clearer thanks to the RD 822/1993 (3):

First section, Organization and Personnel, 2nd paragraph, observes that "all the documentation relative to education, experience, skill and job description for scientific personnel, technicians and operating personnel shall be maintained and archived."

It is obvious that a description of duties assigned to each individual should have been established in writing. Personnel also have to understand their duties, and if necessary they should be trained to carry them out properly. The GLP principles also state that the responsibilities of quality assurance personnel should be written in job descriptions.

A quality system should not be limited to manufacturing operations but also has to cover the overall management of activities in the company, the final costumers, the dealers, and the suppliers.

In order to establish a quality assurance system, the companies usually refer to ISO 9000 Series (which represents the outgrowth of uniform standards originating in Europe), published in March 1987. These standards were developed in December 1987 by the International Organization for Standardization (ISO) in Geneva. Since then, the EEC Member Countries have been invited to jump on the ISO 9000 bandwagon as a foundation for continuous process improvement. Moreover, the ISO 9000 Series has been adopted, word for word, by the Spanish Organization for Standardization and Certification (AENOR) as UNE 66-900 Series of Standards. The ISO 9000 Series of Standards (3) points out that all personnel should have their responsibilities as well as their position in the hierarchy recorded in written instructions. It is particularly remarkable how these standards emphasize the training of inspectors and auditors (refer to Table 1: requirements for implementation of each of the four ISO 9000 Series of Standards).

After reviewing the previous regulations [the same aspects are found in other international regulations such as WHO and PIC (4)], some basic criteria could be established in order to define and implement job descriptions:

1. To confirm a consolidated *program of quality assurance* within a company which has been operating effectively for a certain time: At least 2 years are reckoned to be necessary for implementing a quality assurance program in an average company. This would imply that about 80–90% of the standard operating procedures are written and followed.
2. To have a *diagram* of all the staff showing the responsibilities and levels of authority assigned to each individual: This diagram should be known and understood by all the staff, its aim being to avoid authority gaps, to emphasize the functional independence between the departments of production and quality control, and to avoid responsibility overlaps between them.

Table 1

Requirements for Implementation of ISO 9000 Series of Standards

ISO 9004:
Paragraph 5.2.2 is quite restrictive when asserting that "all activities contributing both directly or undirectly to Quality should be identified and *documented*." For this purpose it is necessary to:

a. Define explicitly both the general and specific responsibilities relating to quality.
b. Establish a system to delegate responsibilities and authority to designated individuals so as to avoid gaps or unexplained overlaps in responsibilities of that personnel concerned with quality matters and to attain the overall quality objectives with the desired efficiency.

ISO 9003:
Paragraph 4.1.2.1 reads as follows: "The responsibilities, authority and interrelations of all levels of personnel in charge of conducting the final inspection and/or performing control tasks should be defined."
ISO 9001 and 9002:
Paragraph 4.1.2.1 states the following: "The responsibilities, authority and interrelations of all personnel who manages, performs and verifies any task relating to quality should be defined and, in particular, of that personnel who requires organizational independence and authority to:

- Start actions to prevent recurrent non-conformities from appearing.
- Identify and document any quality problem detected in the products.
- Start, recommend or contribute with corrective measures through the established channels.
- Verify that the corrective actions are underway.
- Control the treatment, release and storage of a defective product until the deficiency or unsatisfactory situation has been solved.

3. To have *training programs* dealing with quality matters going on or already fully developed: During these training sessions the sense of quality should be instilled in all personnel. Moreover, it should be verified that the commitment of personnel with quality is clearly understood.
4. To have the firm purpose of implementing a total quality assurance program: The management of the company shall be aware of the invesment needed and of the benefits they are likely to obtain if the program is to be successfully completed. In this sense, it is highly recommended that the program be assessed by an external company highly experienced in the development of total quality plans.

DEVELOPMENT OF JOB DESCRIPTIONS

Apart from the legal reasons already mentioned, the development of job descriptions could also lead to a clear improvement in both the *organization* and the *competitivity* of the company. Companies tend to develop systems of management and production which are perfectly functional but static and therefore unable to proceed to continuous improvement, which is basically what a quality assurance system requires in the first place.

At this moment, a thorough analysis of all the positions can actually give way to results considered appalling by production managers:

- There are certain sorts of personnel (technicians and supervisors) who like to collect responsibilities and tasks to excess. This can seriously affect quality and, as a result, it can cause a bad and inadequate quality management, although the production works out well: staff will probably not detect failures on documentation, on in-process controls, or they will perform nonrepresentative samplings and so forth.
- On the other hand, there are personnel who show up apparently "unloaded" of work and could be actually fully utilized, but during inactive periods they do not have the ability or the authority to settle changes in their respective tasks.

A better use of personnel will result in a better use of the means available and eventually in an improvement of productivity with the smallest investment. To avoid

making these thoughts "traumatic" for the personnel, the objectives must be clearly set forth:

- Create job descriptions perfectly adapted to the tasks and duties, tending to avoid extra jobs or loosening of personnel.
- Tighten the commitment of personnel to production processes, on account of which an individual is made more responsible for his or her task, more independent and therefore more motivated. If the person is involved, he or she will feel that something worthwhile has been accomplished and will have a more positive attitude about the job and chances for advancement.
- As operations are conducted by well-trained personnel (individuals who know and understand their job descriptions, who have received ongoing training and are capable of performing their duties reliably), the required quality of products is much more easily obtained, and therefore the number of returned and/or rejected products decreases, the performance of a certain machine improves, and so forth.

On the contrary, certain companies do not believe in quality systems; their slogan is "While we sell whatever we have, it is no use bothering about quality matters." They do not actually realize that certifications of quality of their products and services are likely to be demanded by customers because the benefits coming from quality are taken for granted. They usually expound diverse arguments such as the following:

- *I have no interest in defining the posts because personnel could perform tasks other than those assigned to them, if necessary.*
- *Personnel could overvalue themselves and consequently ask for a better salary.* A reasonable negotiation of the salary rise according to the improvement in duties (e.g., higher output of a machine), would imply a step ahead for the company as well.
- *Supervisors, on being deprived of certain tasks and responsibilities traditionally reserved to them may appear undervalued in the updated job descriptions, being then less motivated towards production or being even able to boycott it.* In such a case the quality assurance programme has not been developed properly and the required commitment of managerial personnel has not been achieved. Under such circumstances, the program can by no means succeed.

EDITING OF JOB DESCRIPTIONS

It is convenient when writing a job description is to have a standard sheet or form which is filled in according to the needs. For example, administrative positions will require a more detailed statement in certain sections whereas production line operating personnel will need wider specifications in other areas. That is to say, each position requires more detail in those sections relevant to its responsibilities.

Personalized (containing name and surname of the person who performs the said job) or general job descriptions might have to be written, depending on the company's activities and on the number of similar posts; whether the duties correspond to specially skilled individuals or whether the responsibilities or tasks are plainly distinctive can also have an influence.

According to our experience, a job description should include the following elements. These can be taken as a reference, simply adding or excluding the irrelevant parts, where a job description to be written:

1. General information: department and so forth
2. Specific attributes of/for the job: education, experience, etc.
3. Functions
4. Equipment to operate
5. Responsibilities and definite tasks

1. Introduction

- Department
- Position title and grade
- Other: shifts, incentives

The department to which the job description refers and its code number should always be specified. Apart from these, other specific items should be included such as position title and grade. For example: head of production, quality control analyst, sample collector, first-line supervisor; the shift (night shift, day shift, part-time job). Whether the job is incentivated or not has to be also shown, as well as the direct or indirect condition of the incentive.

2. Specific Attributes of/for the Job

Education

- Required according to needs
- Advisable
- Qualifications or specific abilities

We refer to the *least education* that an individual should have received so as to perform properly his or her duties—schooling, university degree, etc.—and also to *advisable knowledge* such as specialized and proficiency courses which, even though not being essential for the job, it would be advisable for the individual to have completed.

As far as special abilities and qualifications are concerned, it is useful for employees to get to know the environment, the procedures of the work areas they relate with, and so forth.

Experience

- Required according to the needs
- Advisable

The experience or basic training needed to enable the development of the tasks reliably is of the utmost importance. For example, before working in clean areas as production operating personnel, it is necessary to have prior experience as assistant in such areas (for about 6 months, for example).

Taking the aforementioned employee as an example, having extra knowledge on other aspects of the job would be interesting too: ability to organize the daily work (just as to prevent contamination), knowledge on filtration procedures, readiness with metric system conversions, and so on.

Others Specific Attributes of the Job

Account must be taken of the following: whether personnel should wear special clothes (for instance, sterile single trouser suit) or respect strict safety measures; whether they will handle toxic or hazardous products or be exposed to certain levels of noise above the optimum.

3. Functions

- Immediate reliance on . . .
- Immediate supervision over . . .
- In case of absence replaced by . . .
- Relations with other areas/departments (internal, external)

It should be clearly defined which areas, processes, products, and/or departments are under the employee's responsibility and what is the extent of the said responsibility. Whether the employee has full authority to decide the adequate corrective measures before a failure or whatever incidence may have occurred has to be specified. Whether the writing of annual reports is a part of the employee's responsibilities or whether he or she works by annual objectives (depending on the position) has also to be borne in mind.

4. Equipment to Operate/Supervise

Personnel must have knowledge on operation, control, cleanliness, calibration, checking, and tuning up of the equipment and premises of which he or she is in charge.

5. Responsibilities and Definite Tasks

Following is a list of the main tasks corresponding to each individual. Taking the production operating personnel assigned to clean areas as an example, their basic duties would be:

- Daily control of environmental and work conditions in clean areas (previous to its use)
- Operation of the autoclave (loaded from the inside of clean areas)
- Programming of the autoclave
- Cleaning of aseptic areas
- Perform line clearance and document this operation in the corresponding batch-processing records
- Instruct new employees in safety matters related to clean areas, in quality topics, and in the principles of Good Manufacturing Practice
- Other

MONITORING AFTER JOB DESCRIPTIONS ARE WRITTEN

Every task enumerated in the job descriptions of the company has to fit exactly with realities. Needless to say, it is utterly useless to have written job descriptions simply for compliance. Moreover, most of the tasks may require previous training and/or proficiency courses on the part of personnel. It would be interesting as well to organize training sessions every so often so as to assure that personnel remain familiar with GMP requirements applicable to them and to assess the practical training effectiveness. When purchasing new machines and/or new production lines, personnel assigned to them will assume new responsibilities and therefore will have to be trained on that score, which also has to be recorded in the job descriptions.

Table 2

Job Description of Head of Sales

DEPARTMENT: SALES	CODE OF DEPARTMENT: 267
POSITION: Head of sales	Job description N°: 267/01
Shift: —	Page: —
INCENTIVES: None	Date issued: —

EDUCATION:

Required according to needs: bachelor level or equivalent.

Advisable: at least 3 years of university studies (chemical branch: chemistry or pharmacy)

Qualifications or specific abilities:

- Knowledge on accountancy and administrative matters.
- Knowledge on GMP regulations.
- Aptitude for dealing.
- Spoken languages: English, French, Spanish, etc.

EXPERIENCE:

Required according to needs: at least 3 years working as assistant of the head of sales in the same company or 5 years in another company of the same branch.

Advisable: 1 year as Laboratory technician; 1 year working in the administrative department of a pharmaceutical firm.

ATTRIBUTES OF THE JOB:

- Manage and direct dealings with suppliers.
- Weekly trips.
- Work by annual objectives; annual appraisal.
- Work jointly with the remaining departments of the laboratory such as quality control, production, etc.

EQUIPMENT TO HANDLE:

Use of computer software for planning, control of stock, etc.

FUNCTIONS:

Functions: Looks into the furnishing of raw materials, packaging materials, and general supplies for the laboratory: management of standard stocks.

Tasks:

1. Manage and perform suppliers' certifications (together with the departments of quality assurance, production, and quality control).
2. Maintain the minimum stock needed in the company.
3. Keep files of accepted suppliers; keep lists of current prices of materials.
4. Deal with costs of materials: he/she looks for the most convenient suppliers according to quality/price rate.
5. Arrange and negotiate contract analysis of materials with suppliers.
6. Conduct the return of goods which do not adhere to specifications.
7. Procure the payment of materials together with the accounting department.
8. Maintain updated documentation relative to specifications for materials.
9. Maintain the technical documentation of the department updated: procedures, records, etc.

It is very useful to have individual training sheets for every employee in the company (see Tables 2 and 3) which contains the training needed in the particular operations that the employee performs.

Should an employee be considered for promotion, his or her training sheet should be reviewed and the appropriate training plan for the new job should be scheduled. In this way it can always be proved that the employee has the skill and training that the job description asserts.

From a broader point of view, once the job descriptions are understood by personnel, the next step would be to "validate" or certify the abilities and performance

Table 3

Job Description of Manufacturing Operator

DEPARTMENT: PENICILLIN AREA — CODE OF DEPARTMENT: 109
POSITION: Manufacturing operator — Job description: 109/25
Shift: Day shift — Page: —
INCENTIVES: Yes (depending on productivity) — Date issued: —

EDUCATION:

Required according to needs: elementary education.

Advisable: 2 years of specific education: chemical branch.

Qualifications or specific abilities:

- Knowledge on GMP, job performance and behavior in accordance with the GMP regulations.
- Be methodical and tidy.

EXPERIENCE:

Required according to needs: has carried out pharmaceutical products manufacturing for at least 6 months, handling complex industrial technology and automated systems, preparing batch production records, performing samplings and in-process controls.

Advisable: Aptitude for mechanics: adjustment and planned maintenance of manufacturing equipment; readiness with metric system conversions.

ATTRIBUTES OF THE JOB:

- Wear special clothes and gloves during 90% of the working day.
- Handle highly toxic chemical materials always under established safety policies.
- Work in separate rooms, with only the minimum number of required personnel present.
- Respect specials standards of hygiene on entering or leaving the area.

EQUIPMENT TO HANDLE:

All equipment needed to manufacture pharmaceuticals such as analytical balances, mixers, agitators, homogenizers, mixing and storage tanks (mobile and fixed), pH meters, etc.

[Consult the Standard Operating Procedures (SOP) for penicillin area equipment.]

FUNCTIONS:

Functions:

- Understand and use procedures needed to keep the other materials and areas free of penicillin contamination.
- Know how to operate and program automated equipment just to solve problems when faced with critical situations.
- Keep and suitably record all data coming from processing in the batch-processing records.

Tasks:

1. Prepare and arrange all material and equipment required for manufacturing.
2. Introduce all the data necessary for programming the automated systems (in accordance with the relevant SOP) as well as data related to manufacturing operations (batch number, the expiry date, etc.).
3. Check labels of starting materials: reception date, described use, strength and physical qualities.
4. Prepare formulations (disolutions, suspensions, etc.) following operating procedures and according to manufacturing orders. Inform the supervisor wherever manufacturing operations may deviate from standard documents.
5. Control that environmental working condicions in the area (temperature and pressure differentials) are adequate.
6. Collect samples, control and adjust the pH of all the formulations prepared.

of the said personnel, which means: submit them to periodic requalifications.

CONCLUSIONS

As a conclusion from the exposition set out herein and also from the authors' experience, it can be stated that a suitable description of positions leads to a clear improvement in the quality of all processes and activities developed in a firm, since quality relies upon people. Employees who have a thorough understanding of their jobs and consequently are fully aware of what is expected of them and perform in their jobs better, are more productive and competent. This has a *real effect* on the firm's needs and goals.

Job descriptions have thus much broader implications in a company which has prospects for advancement against a competitive background. Job descriptions are the starting point of more ambitious and interesting matters such as quality loops, equipment qualification, personnel certification, total quality, and so forth, just to set a few examples.

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