

## Chapter 1

### Introduction

#### 1.1 Host Institution Description

Indonesia's government created an institution that develops a system to supervise drug and food products manufacturing and distribution processes that are effective and efficient as an act of prevention and safety for Indonesian citizens. This institution is National Agency for Drug and Food Control (NADFC) or *Badan Pengawasan Obat dan Makanan* (BPOM), a non-ministerial government institution, which was formed based on Presidential Decree No. 103 year 2001 to observe and suppress crimes related to drugs and food. BPOM has been supervising production and distribution facilities for drug and food, providing guidance on facilities that violate regulations, coordinating with law enforcement officials, regional governments and other cross-sectors. Thus, BPOM has a vision to increase quality, safety and competency of drugs and food products. BPOM mission are to increase the supervision system for drug and food based on risk management to protect citizen, encourage business in providing guarantees and safety of drug and food products, facilitate acceleration of development of the drug and food business sector for businesses, and provide trustworthy management to provide excellent public services in drug and food sector.

BPOM established standard operational procedure (SOP) that will be implemented by drug and food industries. In addition, BPOM performed inspection for certification and ensured the implementation of policies in the drug and food production and distribution process. It releases a standardization of procedure and product criteria before and during distribution period. BPOM coordinates and provides technical guidance to center and regional institutions. Other than that, BPOM also implements action against violations of policies and standards that have been previously set. As a government institution, BPOM has several core values which are service oriented, competent, accountable, harmonious, loyal,

adaptable and collaborative. This value strengthens the work culture in government institutions to achieve individual performance and organizational goals.

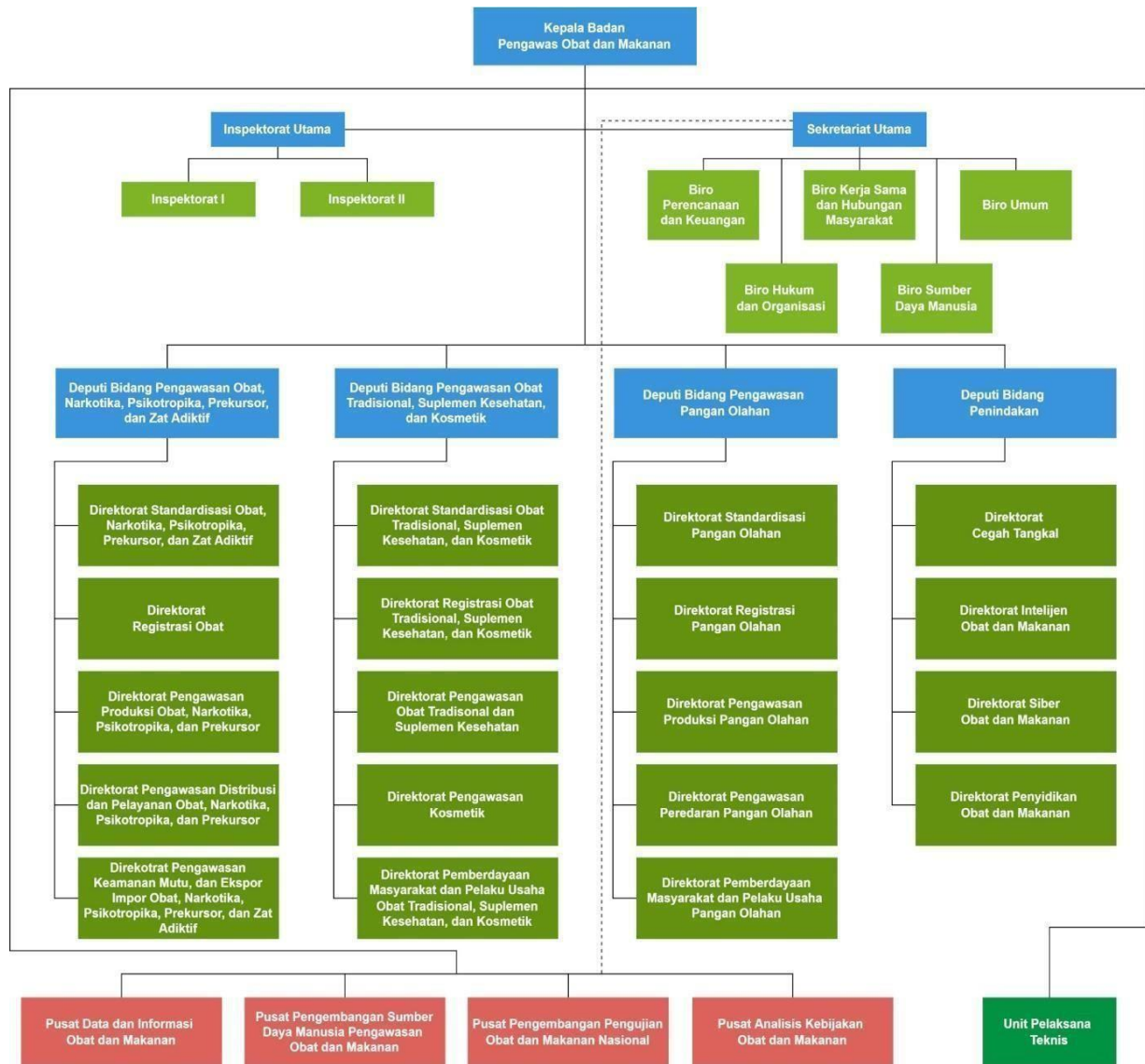


Figure 1. Organizational Structure of National Agency Drug and Food Control (NADFC)

Based on Figure 1. BPOM structure of organization mainly has four divisions which are usually called as field deputies, responsible directly to the head of BPOM. Each field deputy work is supported by 4 to 5 sub-directorates. First of all, *Deputi Bidang Pengawasan Obat, Narkotika, Psikotropika, Prekursor, dan Zat adiktif* or Deputy I, has a function to construct technical policies on drugs, psychotropic, precursor, narcotics and addictive substance. Deputy I also manage 5 sub-directorates which are

directorate of drug registration, directorate of drugs, psychotropic, precursor, narcotics and addictive substance standardization, directorate of quality control and export import. Additionally, there are directorates of production supervision and distribution control of drugs, psychotropic, narcotics and precursor. Next, *Deputi Bidang Pengawasan Obat Tradisional, Suplemen Kesehatan dan Kosmetik* or Deputy II, has a function to establish and implement policies on traditional medicine, health supplement and cosmetics. Deputy II manages 5 sub-directorates, which are directorate of traditional medicine, health supplement and cosmetics standardization and registration, directorate of traditional medicine and health supplement supervision, directorate of cosmetic supervision, and directorate of community and business empowerment in traditional medicine, health supplements, and cosmetics. Furthermore, *Deputi Pengawasan Pangan Olahan* or Deputy III, also constructs technical policies related to the food sector and manages 5 sub-directorates which are the directorate of standardization, registration, production supervision and post-market supervision of processed food. In addition, the fifth sub-directorate is called community and business empowerment of processed food. Lastly, the fourth directorate, *Deputi Bidang Penindakan* or Deputy IV manage 4 sub-directorates which consist of directorate of prevention, drug and food intelligence, cyber, and inspection. Deputy IV has the obligation to establish and implement policies against violations of national regulations on drug and food supervisions.

Besides that, there are inspectorate, secretaries and technical executive units that are also directly responsible to the head of BPOM. Outside the field deputies, the head of BPOM is supported by data and information center, human resources development center, drug and food testing center, and policy analysis center.

## 1.2 Department Description

Direktorat Pengawasan Produksi Obat, Narkotika, Psikotropika, dan Prekursor (DITWASPROD ONPP) or Directorate of Production Supervision of Drug, Narcotics, Psychotropics, and Precursors is a sub-directorate of Deputy I BPOM that more specifically this sub-directorate construct and implement

policies, standard procedures, conduct inspection to production facilities, and set criteria for technical guidance, supervision, and evaluation of drug, narcotics, psychotropics and precursors products. The scope of supervision by DITWASPROD ONPP is the pharmaceutical industry ( production of medicinal raw materials, finished medicines with chemical active substances, and local or imported biological products production facilities) and special facilities such as Blood Transfusion Units (BTU), research institutes, stem cell processing facilities, and radiopharmaceutical processing/production facilities.



**Figure 2.** DITWASPROD ONPP structural organization

Based on **Figure 2**, DITWASPROD ONPP has nine divisions which consist of quality management system (QMS) team, electronic-based government system or *Sistem Pemerintahan Berbasis Elektronik* (SPBE) team, Internal Control System of Government or *Sistem Pengendalian Internal Pemerintah* (SPIP) team, Administration team, production facilities of ONPP supervision team and import export team, production facilities of biologics supervision team, production facilities of ONPP raw materials supervision team, certification and inspection production facility team. Each team staff is responsible to the head of the team mentioned above and the head of each team reports directly to the director of DITWASPROD ONPP.

Furthermore, every division has their respective task to ensure the quality and safety of drug, narcotics, psychotropics, and precursor production. For instance, the QMS team has an important role in creating

standard procedures and acceptable criteria for inspection and certification of drug, narcotics, psychotropics, and precursors production facilities to ensure the quality of the product that is going to be released. SPBE team responsible to maintain a system and ensure implementation of information and communication technology that provides services to the community using electronics. SPIP team's main function is to ensure the enforcement of SPIP. The SPIP is a continuous process of actions carried out by all personnel to provide sufficient confidence in accomplishing organizational targets via effective activities, financial reporting reliability, state asset security, and adhering to regulations and laws. Administration team conducts plan preparation, programs and budgets, financial management and state property, communication and information technology, monitoring, evaluation and reporting, personnel affairs management, archives, correspondence management, and quality assurance administration. For the production facilities supervision team, the scope of work is material preparation for policy establishment, policies implementation, setting standard, technical training and supervision material, and application of supervision, evaluation and report for assessment and facilities inspection that is respective to each division team category. Additionally, the production facilities supervision team for drugs, narcotics, psychotropics, precursor, import export products need to conduct routine assessment and inspection directly to the production facilities and special facilities.

During the 2 months of internship period, the author was given the opportunity to work under the supervision of the head of the administration team. However, he managed to assign me to five different divisions each week which are the certification team, inspection team, production facilities supervision of drug raw material, import export, and biologic products. The author was assigned with several tasks for each division and the work was submitted and discussed with the head of each team before being reported to the head of the administration. Based on the annual report, DITWASPROD ONPP conducts socialization to pharmaceutical industries and special facilities like blood transfusion unit (BTU). They also routinely do planned and unplanned inspections to those facilities to ensure the regulation compliance of the production facility. Meetings are also done to communicate information on organizational level and opportunity to improve future performance of DITWASPROD ONPP.