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Healthcare & Life Sciences

# Assignment Specification Director of Clinical Development

Prepared for:

SANOVI PASTEUR 

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## Company Information

Sanofi Pasteur is the vaccines division of Sanofi, a global biopharmaceutical company focused on human health. In existence for over a century, the company has a long-standing history and commitment to the development, coverage, and distribution of vaccines for the betterment of public health. Vaccines comprise a significant amount of Sanofi's entire revenue stream and the company has re-invested almost 16% of its profits into its Research and Development efforts for over fifteen consecutive years.

While vaccine awareness has increased significantly in the last seventeen months, Sanofi Pasteur has long been dedicated to the elimination of diseases that are preventable through immunization. Sanofi Pasteur's portfolio of vaccines targets both bacterial and viral diseases, includes the following:

- Cholera
- Dengue
- Diphtheria
- *Haemophilus Influenzae* Type B
- Hepatitis A
- Hepatitis B
- Influenza
- Japanese Encephalitis
- Meningococcal Meningitis
- Pertussis
- Poliomyelitis
- Respiratory Syncytial Virus
- Rabies
- Tetanus
- Typhoid Fever
- Yellow Fever

Sanofi Pasteur's commitment to R&D is also evident with eight product candidates currently in Phases I and II, and another three currently in Phase III. New Sanofi Pasteur product candidates in development target multiple diseases including Pediatric Influenza, Yellow Fever, Meningitis B, and Rabies. Other vaccines in development with partner companies include those targeting RSV, Herpes simplex virus Type 2, Pneumococcal, and COVID-19. Utilizing mRNA technology, multiple new vaccine targets are also expected in the very near future.

For many years, the Sanofi Pasteur manufacturing sites producing seasonal influenza vaccines had been prepared to switch its production to a pandemic influenza vaccine, should it be necessary. Because of this preparedness at these top manufacturing facilities, Sanofi Pasteur has been able to support the production of multiple COVID-19 vaccines available for global immunization efforts including those developed by Moderna, Johnson & Johnson, and BioNTech (Pfizer).

Sanofi recently announced the launch of a dedicated mRNA Center of Excellence, to which approximately \$470 million will be invested annually to accelerate the end-to-end R&D of next-generation vaccines. The focus will be on innovating mRNA vaccines beyond pandemic to routine use in diseases with high unmet need. Sanofi's mRNA portfolio was established in 2018 and with the establishment of this Center of Excellence, a minimum of six clinical candidates are expected by 2025.

Sanofi currently employs over 100,000 individuals in over 100 countries.



## Position Description

**Position title:** Director, Clinical Development

**Reports to:** Clinical Franchise Leader

**Location:** Swiftwater, PA, USA

### Reason for role and position summary

The Director of Clinical Development will be part of the department of Global Clinical Development Strategy and report directly to the Clinical Franchise Leader. The position will be based in Sanofi Pasteur's North American headquarters located in Swiftwater, Pennsylvania. The Director of Clinical Development will be responsible for serving as the subject matter expert and clinical strategy lead in the global clinical development of multiple vaccines, supporting the development and commercialization of Sanofi Pasteur's portfolio of vaccine projects. In addition to providing strategic clinical leadership, you will also play a key role in ensuring success and efficiency at an operational level.

The Sanofi Pasteur Clinical Development Strategy team is responsible for designing and conducting all pre-licensure clinical trials for the organization on a global basis. The Global Clinical Development Strategy team is working closely with the different operational platforms in the department of Global Clinical Development. Clinical trials are conducted to support vaccine products in pipeline and are conducted internationally, depending on the geographic location of the affected areas and populations.

Additionally, the Global Clinical Development Strategy team provides support to vaccines not yet entered in clinical trials. Novel, creative areas of research are always explored by the Sanofi Pasteur organization to complement its already successful and proven pipeline and portfolio of vaccines. The Global Clinical Development Strategy team also supports Global Medical Sciences and Brand Teams on late-stage programs designed to generate evidence of efficacy and effectiveness of vaccines used to profile the label, pricing and positioning of the vaccines in the market.

The Global Clinical Development Strategy team at Sanofi Pasteur's Swiftwater headquarters site is positioned to expand. The group has established multiple positions to strengthen the company's ability to develop new vaccines necessary to support multiple disease clinical activity. Areas of focus include Influenza, Meningococcal, Poliomyelitis, and COVID-19 but, if necessary, the positions will also support or lead clinical development in other vaccine areas.

It is important for the new Director of Clinical Development to work collaboratively with existing Clinical Development Strategy colleagues and other internal team members in the field, as well as Key Opinion Leaders, healthcare professionals and health authority stakeholders.



It is essential that the right person believes in the positive impact that industry can make in the advancement of vaccines. The Global Clinical Development Strategy team presents one consistent voice within the global vaccines community and this person should continue to deliver and embody this message. This role is vital to the company and this person will be a central player within the Global Clinical Development Strategy team.

### Influenza

The World Health Organization (WHO) estimates that the number of influenza-related deaths ranges between 290,000 to 650,000 per year. Each year, the composition of seasonal influenza vaccines is adapted to the dominant strain in circulation. Several forms of vaccine are available.

In contrast to seasonal influenza, an influenza pandemic is unpredictable and occurs when a flu virus evolves and travels rapidly around the world infecting a great number of people. It may cause the rapid development and production of a new vaccine. Fortunately, all Sanofi Pasteur manufacturing facilities producing seasonal influenza vaccines are designed to switch to the production of a pandemic influenza vaccine should it be necessary.

Currently in the pipeline is a Phase II vaccine targeting pediatric flu. Additionally, Sanofi Pasteur has partnered with Translate Bio, a clinical-stage messenger RNA (mRNA) therapeutics company, to develop an mRNA-based investigational vaccine against seasonal influenza. This vaccine has initiated its Phase I trial, which will evaluate the potential for the next generation of influenza vaccines.

### Meningococcal

Meningococcal disease can be caused by multiple bacteria, most of which can be prevented by vaccination. Without extremely prompt treatment, infection can be fatal or cause great harm. The WHO estimates over 290,000 deaths were caused in 2017 by meningococcal disease. As many as one of five people who contract the infection have serious complications. The CDC estimates that about 15% of those who survive the illness are left with disabilities that include deafness, brain damage and neurological problems. The main causes of bacterial meningitis include meningococcus, pneumococcus, *Haemophilus influenzae* and group B streptococcus. The WHO is committed to eradicating the disease by 2030.

Sanofi Pasteur has contributed to the successful development and advancement of meningococcal vaccines for over 45 years. In addition to its portfolio of existing vaccines, the company's commitment remains steadfast with multiple Phase III clinical trials underway in both the US and EU. An additional Phase I/II trial targeting Meningitis B is also underway.

### Childhood Immunizations

Sanofi Pasteur has long contributed to the eradication of and immunization against multiple childhood diseases. Already in the company portfolio are vaccines and combination vaccines targeting diseases including Polio, Pertussis, Hib. In February of this year, the CDC included a



new combination vaccine, Vaxelis, as an option in the CDC's Child and Adolescent Immunization Schedule. The vaccine was developed through a partnership with Merck and is the first and only hexavalent combination vaccine available in the US. It includes ingredients for Diphtheria, Tetanus, Pertussis, and Polio from Sanofi Pasteur and ingredients for Hib and Hepatitis B from Merck.

## COVID-19

Sanofi Pasteur currently has two COVID-19 vaccine initiatives in process. The first is their effort with GSK utilizing an adjuvanted recombinant-protein COVID-19 vaccine candidate. Enrollment in their Phase III clinical study has begun in over 20 countries in Asia, Africa, Latin America, and the US. The strategy includes a two-stage approach with the first stage targeting the original strain of the virus (Wuhan) while the second stage targets a second variant (South African).

The organization's second COVID-19 vaccine initiative includes the company's mRNA candidate, developed with Translate Bio, that is currently in Phase I/II. The study includes 415 participants across 13 investigational sites. The team is working to improve the temperature stability of the vaccine candidate.

### Key Responsibilities:

- Medical monitoring of clinical trials to maintain patient safety
  - Compliance with ICH-GCP guidelines
  - Communication with principal investigators and study site coordinators in order to address any scientific and medically related inquiries
  - Act as the medical expert on call for site audits and inspections (will delegate as appropriate to regional colleagues)
  - Review and report all serious and non-serious adverse events
  - Current with SOP training and maintains up-to-date training records
- Clinical trial management from research to licensing, including ownership and strategic direction of Clinical Development Plans (CDP) and the subsets of the Common Technical Document (CTD)
  - Contribution to the strategic vision of the project and support the project team as a member of Clinical Sciences
  - Liaise with Senior Director/ Clinical Franchise Leader to ensure CDP is aligned with Franchise objectives
  - Ensure clear, timely and consistent strategy definition across the clinical trials reflected in the CDP
  - Utilize innovative and cost-effective clinical trials to generate data that support labelling, pricing and positioning of new vaccines
  - Organize the CDP to encompass plans for three to five years
  - Lead the interpretation and critical evaluation of study results
  - Contribute to the generation and submission of documentation to Regulatory and Health Authorities including Clinical Study Reports and INDs
  - Interact with global Sanofi Pasteur employees for future US trials and compliance



- Oversee the operational aspects of the clinical trials and interact with internal team members and external clients
- Ensure the timelines and quality requirements of trials are clearly communicated and followed
- Be a contributing member of the Clinical Development organization
  - Responsible for the overall performance of the clinical team, including global members of clinical and non-clinical operational activities
  - Timely and accurate accomplishment of key project milestones including the design of the clinical development strategy, licensure submissions, and integration of clinical data for milestone decision processes
  - Participate actively in process improvement and other initiatives
  - Ensure that the Clinical Development Plans, Study Protocols and Study Reports are reviewed with the relevant internal governance committees to ultimately present documentation to regulatory agencies (FDA, EMA, etc.)
  - Interact with the Program Managers, other Franchise Leaders and other internal members in a positive and collaborative manner
  - Work as a project team member
    - Coordinate multi-departmental input for writing and capturing data
    - Coordinate and interact with corporate committees for budgeting for clinical trials and presentation of CDPs
    - Periodically review all safety data from all ongoing clinical trials as a member of a Safety Management Team
  - Preparation of presentation materials including study results internally to senior management and externally to investigators, outside partners, regulatory agencies and public health agencies
  - As appropriate, serve as ambassador for Sanofi Pasteur:
  - Representing the Company in conferences (international and domestic)
    - Author publications
    - Establish, develop and maintain a network of Key Opinion Leaders (KOLs) and leading scientists in the field

## Your credentials

### Candidate Profile:

- Experience in Infectious Diseases, vaccines preferred, in industry, public health or public sector
- Clinical trial experience preferred; experience adhering to GCP/ ICH guidelines
- Bench experience a plus
- Ability to work on multidisciplinary teams
- Understanding and sensitivity to international and global interactions a strong plus
- Training in epidemiological methods very advantageous
- Excellent verbal and written communication skills in English mandatory

### Education:

- M.D. highly desirable with good experience in Vaccines
- Infectious Diseases certification highly desirable; Clinical Immunology welcome



#### Personal Characteristics:

- Demonstrated organizational skills
- Ability to network and communicate clearly
- Natural leadership and ability to motivate teams
- Personal drive to surpass timelines on projects
- Ability to multitask and re-prioritize
- Ability to work well under pressure
- Positive and welcoming personality
- Intuitive drive for novel science

#### Performance Expectations

Performance expectations in the first year include:

- Assimilate into the internal Clinical R&D team on a global scale - this includes working well with international Clinical Sciences and Clinical Program teammates as well as internal Project Leaders and other relevant disciplines
- Ensure that project timeline and quality milestones are met
- Contribute to the strategic vision of assigned vaccines
- If required, an adjustment to the industry environment and setting

#### Useful links

[www.sanofipasteur.com](http://www.sanofipasteur.com)

[www.sanofi.com](http://www.sanofi.com)

<https://www.sanofi.com/en/media-room/press-releases/2021/2021-06-29-10-00-40-2254458>

Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).