

SPEED POST

No.A.11018/11/2021-DR
Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
(Drugs Regulation Section)

Nirman Bhawan, New Delhi
Dated 1st June, 2022

To

The Administrative Officer
National Institute of Biologicals,
A-32, Sector-62,
Noida- 201309.

Subject: Amendment of recruitment rules for the Scientific Posts at NIB
- Regarding.

Sir,

I am directed to refer to your letter No.A.2-48/2021-NIB/101 dated 07.04.2022 on the subject cited above and to convey the approval of Secretary (HFW) and Chairman, Governing Body, NIB for amendment of recruitment rules for the following Scientific posts as per the Annexure in terms of decision taken in the 30th Governing Body meeting of NIB held on 12.07.2021 vide agenda item No.4:

- (i) Dy Director(QC) Pay Matrix Level-14 Rs.144200 - 218200/-
- (ii) Scientist Grade-I Pay Matrix Level-13 Rs.123100-215900/-
- (iii) Scientist Grade-II Pay Matrix Level-12 Rs.78800-209200/-
- (iv) Scientist Grade-III Pay Matrix Level-10 Rs.56100-177500/-
- (v) Junior Scientist Pay Matrix Level-7 Rs.44900-142400/-

Yours faithfully,

Digitally Signed by Bikash
R Mahato
Date: 01-06-2022 12:08:51
Reason: Approved

(Bikash R Mahato)

Under Secretary to the Government of India
Tele # 23061141

Copy to

1. The Director, National Institute of Biologicals, A-32, Sector-62,



Noida- 201309.

Annexure**Recruitment Rules for the post of Dy Director (QC)**

1	Name of the post	Dy Director (QC)
2	No. of Post	2 (Two)
3	Classification	Group 'A' (Non-Ministerial)
4	Scale of pay	Pay Matrix Level-14 Rs.144200 - 218200/- + NPA for medical Personnel subject to rules.
5	Whether Selection post or Non-Selection post	Selection
6	Age limit for direct recruitment	Not applicable.

7	Educational and other qualification required for direct recruitment	<p><u>Medical</u> A. Essential</p> <p>i. MBBS from MCI recognized Medical College.</p> <p>ii. PG Medical degree in the field of Microbiology/Biochemistry/ Immunohematology & Blood Transfusion / Pharmacology / Bacteriology / Serology / Hematology from the recognized University</p> <p>or</p> <p>(iii) Ph. D in any of the above related field.</p> <p>Experience : Experience of 12 years in research, training production and quality control of Biologicals after acquiring the essential qualification in Govt/Pvt. Laboratories of repute.</p> <p><u>Non Medical</u> A. Essential</p> <p>i) Masters degree in Microbiology / Clinical Microbiology / Biotechnology/ Bioinformatics/ Biochemistry / Bacteriology / Physiology / Pharmacology/ Serology / Molecular Biology from any recognized University with at least 60% marks.</p> <p>ii) Ph. D in any of the above related fields.</p> <p>Experience : Experience of 12 years in research, training production and quality control of Biologicals after acquiring the essential qualification in Govt/Pvt. Laboratories of repute.</p> <p>Note. Depending upon the requirements, the exact Essential Qualification and areas of experience shall be specify by the Director of the Institute at the time of recruitment.</p>
8	Whether age & qualifications prescribed for Direct Recruitments will apply in the case of Promotes.	<p>Age : No</p> <p>Qualification: As per column No11</p>
9	Period of probation	One year

10	Method of recruitment whether by direct or promotion or by deputation /transfer & percentage to be filed by various methods.	Promotion by DPC.
11	In case of recruitment by promotion/deputation transfer grade from which promotion/deputation transfer to be made.	Promotion: Scientist Grade-I of the Institute having rendered 3 years regular service in the grade of Pay Matrix Level-13 and Possessing the educational qualification prescribed for Direct Recruitment
12	If a Department promotion committee exists what is its composition	As per NIB Bye-laws.
13	Duties	He will be overall in charge of the protocol and sample control section, Bacterial product section, Viral product section, Blood product section, Immunodiagnostic section, Recombinant product section, Bio-assay section etc. He is expected to develop and maintain standards to ensure continued safety, purity, potency and effectiveness of biological products, develop procedures for review and evaluation of biologicals products guide the testing of products submitted for release; to arrange for inspection of manufacturing facilities; to coordinate with Drug Controller General (India), Government of India & International Agencies and manufacturers on issues related to quality control of biologicals products. He will assist the Director in the implementation of the science programme as may be required.

Recruitment Rules for the post of Scientist Grade-I

1	Name of the post	Scientist Grade-I
2	No. of Post	4(Four)
3	Classification	Group 'A' (Non-Ministerial)
4	Scale of pay	Pay Matrix Level-13 Rs.123100-215900/- + NPA for Medical Personnel

5	Whether Selection post or Non-Selection post	Selection
6	Age limit for direct recruitment	Not Exceeding 50 years
7	Educational and other qualification required for direct recruitment	<p>A. Medical (Essential):</p> <p>i. MBBS from MCI recognized Medical College.</p> <p>ii. PG Medical degree in the field of Microbiology/Biochemistry/ Immunohematology & Blood Transfusion / Pharmacology / Bacteriology / Serology / Hematology from the recognized University</p> <p>and</p> <p>i. 10 (Ten) Years' relevant experience after acquiring essential qualification</p> <p>B. Non Medical (Essential)</p> <p>i) Master in Microbiology / Clinical Microbiology / Biotechnology/ Bioinformatics/ Biochemistry / Bacteriology / Physiology / Pharmacology/ Serology / Molecular Biology from any recognized University with at least 60% marks..</p> <p>and</p> <p>ii) A minimum of Ten years' of relevant experience in any of the following areas:</p> <p>a) Quality Control Testing of Biologicals and Biotherapeutics;</p> <p>b) Review of Technical Dossiers of Biologicals and Biotherapeutics including Vaccines in respect of Chemistry Manufacturing Control (CMC), non-clinical trial data on Animal Pharmacology/Animal Toxicology, Clinical Trial data;</p> <p>c) Review of Technical Dossiers of 'In Vitro Diagnostic (IVD) Medical Devices' in respect of conformation to the Essential Principles of Safety and Performance of Medical Devices which include Product Description, Design and Manufacturing information, Product performance specifications and associated validation and verification studies, Labelling and Regulatory history;</p> <p>d) Evaluation & Review of Adverse Events:</p> <p>i) following Immunization (AEFI)</p> <p>ii) associated with Biologicals and Biotherapeutics (Pharmacovigilance)</p> <p>iii) associated with blood transfusion and blood products administration (Haemovigilance);</p> <p>iv) due to indirect harm associated with IVD</p>

		<p>Medical Devices (Materiovigilance) e) Management of Quality System with application of ISO : 17025 and ISO : 34 with Total Quality Management approach f) Research in Biologicals and Biotherapeutics, or</p> <p>i) Ph.D in any of the disciplines mentioned above in B (i), and, ii) Six Years' relevant experience after acquiring Ph.D Desirable: At least 7(Seven) publications or Articles in Indexed Journals in any of the above mentioned fields of qualification or experience.</p>
8	Whether age & qualifications prescribed for Direct Recruitments will apply in the case of Promotes.	Age: No Qualification As per column No.11
9	Period of probation	One year for Direct Recruits
10	Method of recruitment whether by direct or promotion or by deputation /transfer & percentage to be filed by various methods.	75% by promotion & 25% By Direct Recruitment.
11	In case of recruitment by promotion/deputation transfer grade from which promotion/deputation transfer to be made.	Scientist Grade II of the Institute having rendered 5 years of regular service in the Grade. & possessing the educational qualification prescribed for Direct Recruitment
12	If a Department promotion committee exists what is its composition	As per NIB Bye-laws.

13	Duties	He will direct the scientific review of protocols / plan and conduct research related to the development, manufacture and testing of biologicals; to oversee coordinate and organize testing of biologicals; to oversee, coordinate and organize testing of samples (Bacterial Vaccines, Viral Vaccines, Blood Products, Immunodiagnostics, Recombinants, Bio-assay and Toxicity, Analytical Chemistry, Production of Reference Standards etc.) As chief of each laboratory, he will be responsible for its functioning, coordinate with other Senior Scientists to provide technical support for training, establishment and execution of procedures, evaluation of results. etc. and any other work assigned by the competent authority from time to time.
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Recruitment Rules for the post of Scientist Grade-II

1	Name of the post	Scientist Grade-II
2	No. of Post	10(Ten)
3	Classification	Group 'A' (Non-Ministerial)
4	Scale of pay	Pay Matrix Level-12 Rs.78800-209200/- + NPA for Medical Personnel
5	Whether Selection post or Non-Selection post	Selection
6	Age limit for direct recruitment	Not Exceeding 45 years
7	Educational and other qualification required for direct recruitment	<p>A. Medical (Essential):</p> <p>i) MBBS from MCI recognized Medical College. ii) PG Medical degree in the field of Microbiology/Biochemistry/ Immunohematology & Blood Transfusion / Pharmacology / Bacteriology / Serology / Hematology from the recognized University</p> <p>and</p> <p>i) Five Years' relevant experience after acquiring essential qualification.</p> <p>B. Non Medical (Essential)</p> <p>i) Masters degree in Microbiology / Clinical Microbiology / Biotechnology/ Bioinformatics/ Biochemistry / Bacteriology / Physiology / Pharmacology/ Serology / Molecular Biology from any recognized University with at least 60% marks..</p> <p>and</p> <p>ii)A minimum of 7 (Seven) years' of</p>

		<p>relevant experience in any of the following areas:</p> <p>a) Quality Control Testing of Biologicals and Biotherapeutics;</p> <p>b) Review of Technical Dossiers of Biologicals and Biotherapeutics including Vaccines in respect of Chemistry Manufacturing Control (CMC), non-clinical trial data on Animal Pharmacology/Animal Toxicology, Clinical Trial data;</p> <p>c) Review of Technical Dossiers of 'In Vitro Diagnostic (IVD) Medical Devices' in respect of conformation to the Essential Principles of Safety and Performance of Medical Devices which include Product Description, Design and Manufacturing information, Product performance specifications and associated validation and verification studies, Labelling and Regulatory history;</p> <p>d) Evaluation & Review of Adverse Events:</p> <p>i) following Immunization (AEFI)</p> <p>ii) associated with Biologicals and Biotherapeutics (Pharmacovigilance)</p> <p>iii) associated with blood transfusion and blood products administration (Haemovigilance);</p> <p>iv) due to indirect harm associated with IVD Medical Devices (Materiovigilance)</p> <p>e) Management of Quality System with application of ISO : 17025 and ISO : 34 with Total Quality Management approach .</p> <p>f) Research in Biologicals and Biotherapeutics,</p> <p>or</p> <p>i. Ph. D in any of the disciplines mentioned in B (i) above, and</p> <p>ii. Three Years' relevant experience after acquiring Ph.D</p> <p>Desirable: At least 5 (Five) publications or articles in Indexed Journals, in any of the above mentioned fields of qualification or experience.</p>
8	Whether age & qualifications prescribed for Direct Recruitments will apply in the case of Promotes.	Age: No Qualification: As per Column 11
9	Period of probation	One year for Direct Recruits

File No.A.11018/11/2021-DR

10	Method of recruitment whether by direct or promotion or by deputation /transfer & percentage to be filed by various methods.	By Promotion: 40% By Direct Recruitment: 60%
11	In case of recruitment by promotion/deputation transfer grade from which promotion/deputation transfer to be made.	Scientist Grade-III of the Institute having rendered 10 years of regular service in the grade.
12	If a Department promotion committee exists what is its composition	As per NIB Bye-laws.
13	Duties	He will assist the Scientist Gr. I in carrying out the quality testing of biologicals in the Laboratories and any other work assigned by the competent authority from time to time.

Recruitment Rules for the post of Scientist Grade-III

1	Name of the post	Scientist Grade-III
2	No. of Post	18 (Eighteen)
3	Classification	Group 'A' (Non-Ministerial)
4	Scale of pay	Pay Matrix Level-10 Rs.56100-177500/- + NPA for Medical Personnel
5	Whether Selection post or Non-Selection post	Selection
6	Age limit for direct recruitment	Not Exceeding 35 years

Educational qualification required for recruitment	and other for direct	<p>Essential:</p> <p>A. Medical (Essential):</p> <p>i) MBBS from MCI recognized Medical College. ii) PG Medical degree in the field of Microbiology/Biochemistry/ Immunohematology & Blood Transfusion / Pharmacology / Bacteriology / Serology / Hematology from the recognized University and i) One year experience in the field after acquiring the essential qualification</p> <p>B. Non Medical (Essential)</p> <p>i) Master in Microbiology / Clinical Microbiology / Biotechnology/ Bioinformatics/ Biochemistry / Bacteriology / Physiology / Pharmacology/ Serology / Molecular Biology from any recognized University with at least 60% marks. and</p> <p>ii) A minimum of three years' of relevant experience in any of the following areas: a) Quality Control Testing of Biologicals and Biotherapeutics; b) Review of Technical Dossiers of Biologicals and Biotherapeutics including Vaccines in respect of Chemistry Manufacturing Control (CMC), non-clinical trial data on Animal Pharmacology/Animal Toxicology, Clinical Trial data; c) Review of Technical Dossiers of 'In Vitro Diagnostic (IVD) Medical Devices' in respect of conformation to the Essential Principles of Safety and Performance of Medical Devices which include Product Description, Design and Manufacturing Information, Product performance specifications and associated validation and verification studies, Labelling and Regulatory history; d) Evaluation & Review of Adverse Events: i) following Immunization (AEFI) ii) associated with Biologicals and Biotherapeutics (Pharmacovigilance) iii) associated with blood transfusion and blood products administration (Haemovigilance); iv) due to indirect harm associated with IVD Medical Devices (Materiovigilance) e) Management of Quality System with application of ISO : 17025 and ISO : 34 with Total Quality Management approach . f) Research in Biologicals and Biotherapeutics,</p> <p>Desirable: At least 2 (two) publications or Articles in Indexed Journals, in any of the above mentioned fields of qualification or experience.</p>
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File No.A.11018/11/2021-DR

8	Whether age & qualifications prescribed for Direct Recruitments will apply in the case of Promotes.	Age: No Qualification: As per column 11.
9	Period of probation	Two years for both Direct Recruits & Promotees.
10	Method of recruitment whether by direct or promotion or by deputation /transfer & percentage to be filed by various methods.	By Promotion: 33.3% By Direct Recruitment: 66.6%
11	In case of recruitment by promotion/deputation transfer grade from which promotion/deputation transfer to be made.	Junior Scientists of the Institute having rendered 5 years of regular service in the grade.
12	If a Department promotion committee exists what is its composition	As per NIB Bye-laws.
13	Duties	He will assist the Senior Scientists in carrying out the quality testing of biologicals in the Laboratories and any other work assigned by the competent authority from time to time.

Recruitment Rules for the post of Junior Scientist

1	Name of the post	Junior Scientist
2	No. of Post	22 (Twenty Two)
3	Classification	Group 'B' (Non-Ministerial)
4	Scale of pay	Pay Matrix Level-7 Rs.44900-142400/-
5	Whether Selection post or Non-Selection post	Selection
6	Age limit for direct recruitment	Not exceeding 30 years

7	Educational and other qualification required for direct recruitment	<p>Essential:</p> <p>i) Master in Microbiology / Clinical Microbiology / Biotechnology/ Bioinformatics/ Biochemistry / Bacteriology / Pharmacology/ Serology / Molecular Biology / Physiology from any recognized University with at least 60% marks.</p> <p>and</p> <p>ii) A minimum of one year's of relevant experience in any of the following areas:</p> <p>a) Quality Control Testing of Biologicals and Biotherapeutics;</p> <p>b) Review of Technical Dossiers of Biologicals and Biotherapeutics including Vaccines in respect of Chemistry Manufacturing Control (CMC), non-clinical trial data on Animal Pharmacology/Animal Toxicology, Clinical Trial data;</p> <p>c) Review of Technical Dossiers of 'In Vitro Diagnostic (IVD) Medical Devices' in respect of conformation to the Essential Principles of Safety and Performance of Medical Devices which include Product Description, Design and Manufacturing information, Product performance specifications and associated validation and verification studies, Labelling and Regulatory history;</p> <p>d) Evaluation & Review of Adverse Events:</p> <p>i) following Immunization (AEFI)</p> <p>ii) associated with Biologicals and Biotherapeutics (Pharmacovigilance)</p> <p>iii) associated with blood transfusion and blood products administration (Haemovigilance);</p> <p>iv) due to indirect harm associated with IVD Medical Devices (Materiovigilance)</p> <p>e) Management of Quality System with application of ISO : 17025 and ISO : 34 with Total Quality Management approach .</p> <p>f) Research in Biologicals and Biotherapeutics</p> <p>Desirable: At least 1 publication or an Article in an Indexed Journal in any of the above mentioned fields of qualification or experience.</p>
8	Whether age & qualifications prescribed for Direct Recruitments will apply in the case of Promotes.	Age: No Qualification: As per Column No.11
9	Period of probation	2- Years for Direct Recruits

10	Method of recruitment whether by direct or promotion or by deputation /transfer & percentage to be filed by various methods.	i) 25% by Promotion. ii) 75% by Direct Recruitment
11	In case of recruitment by promotion/deputation transfer grade from which promotion/deputation transfer to be made.	Laboratory Technician with 5 years regular service in the grade and possessing essential Qualification prescribed for Direct recruitment.
12	If a Department promotion committee exists what is its composition	As per NIB Bye-laws.
13	Duties	He will provide technical assistance to the scientists in testing of biological products and setting of reference standards for biologicals and any other work assigned by the competent authority from time to time.