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 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India		
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			SOP No. IPC/PvPI/HR/001
	Division Human Resource	Revision No. 00	Review Date 31/10/2019
Effective Date 01/11/2016			
Title: SOP for the Recruitment of Contractual Employees under NCC- PvPI, IPC			

1.0 OBJECTIVE

To lay down a procedure for recruitment of contractual employee under NCC-PvPI, IPC.

2.0 SCOPE

This SOP Shall be applicable to Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

- 3.1 The designated personnel at NCC-PvPI and Co-ordinators of respective AMCs shall be responsible for adhering to this SOP.
- 3.2 HR division shall be responsible for implementation of this SOP.

4.0 ACCOUNTABILITY

Officer-in-charge-Pharmacovigilance Programme of India.

5.0 PROCEDURE

- 5.1 The recruitment procedure for appointment of contractual employees under NCC-PvPI, IPC shall be initiated after the approval from competent authority.
- 5.2 The appointment for Pharmacovigilance Associate shall be of two level:
- 5.2.1 At NCC Level
- 5.2.2 At AMCs Level
- 5.3 Vacancy notice shall be circulated by the NCC through IPC website/Newspaper/notice board/ Institution notice board. Applications shall be received from the candidates as per Annexure-I.

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE	<i>[Signature]</i>	26/10/2016
Reviewed by	Dr. Pawan K. Saini	Scientific officer	<i>[Signature]</i>	27/10/2016
Approved by	Dr. Kalishwan	PSO	<i>[Signature]</i>	28/10/2016



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5.4 The Screening and Selection committee shall be constituted by the competent authority of NCC, the composition of selection committee shall be as follows:

5.4.1 IPC Nominee

5.4.2 CDSCO (Regulatory Body) – Nominee

5.4.3 AMC Coordinator/Eminent Scientist from reputed organization/Institution.

5.5 After receiving the applications for the said position, screening process shall be done by the screening committee.

5.6 Shortlisted candidates shall go through the written test/interview process at NCC/AMC/CDSCO Zonal offices etc.

5.7 The selection committee for the interview at AMC level shall also be composed by the competent authority of NCC.

5.8 After completion of interview process, committee shall finalise the candidate(s) for the required position, and the list of selected candidates shall be handed to IPC authorised outsourcing agency to issue the offer letter & appointment order.

5.9 At AMCs level after completion of interview, the Coordinators of respective AMCs shall forward all soft/hard copies of the interview documents & list of selected candidates to NCC, and offer letter & appointment order shall be issued from IPC authorised outsourcing agency.

5.10 The competent authority reserves the rights to reject, accept, extend and cancel the appointment without assigning any reason thereof.

5.11 Period of engagement: - The contractual engagement shall be initially for a period of one year which can be extended from time to time based on individual performance or requirement of the department with the approval of competent authority. The engagement can also be terminated any time without giving any reason thereof.

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		27/10/2016
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5.12 The recruitment rules of various post is as follows:

5.12.1 Recruitment rules for Pharmacovigilance Associate Post

1.	Name of the Post	Pharmacovigilance Associate (Contractual)
2.	Salary	As per norms
3.	Educational and other qualifications required	<p>Essential: Minimum Qualification should be MBBS/ BDS/M. Pharm. /Pharm. D from a recognised university. or Post Graduate degree in the relevant field having one year experience in Pharmacovigilance</p> <p>Desirable:</p> <ul style="list-style-type: none"> Proficiency in Computer Applications.
4.	Job Requirements	<ul style="list-style-type: none"> Collection of ADR Reports. Follow up with the reporter/patient for Completeness of ADR as per SOPs. Data Entry in VigiFlow. Reporting to NCC-PvPI through VigiFlow with the source data (Original) attached with each ADR case. Training/Sensitization/Feedback to physicians through newsletters circulated by the NCC- PvPI. Other activities as assigned by competent authority time to time.
5.	Period of Engagement	The engagement shall be initially for a period of one year. The engagement can be extended/curtailed from time to time depending upon the performance of Pharmacovigilance Associate or requirement of the department with the approval of competent authority.
6.	Method of Recruitment	Direct recruitment
7.	Selection Committee	Constituted by the Secretary-cum-Scientific Director

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		27/10/2016
Approved by	Dr. V. Kalai Selvan	PSO		28/10/2016



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5.12.2 Recruitment rules for HR Associate Post

1.	Name of the Post	HR Associate (Contractual)
2.	Salary	As per norms
3.	Age Limit	Not exceeding 30 years
4.	Educational and Other Qualification Required	<p>Essential: MBA in HR from a recognised university preferably with one year experience in administrative and establishment matters in Pharmacovigilance or any other National Health Programme.</p> <ul style="list-style-type: none"> • Knowledge of Computer Application will be preferred.
5.	Job Requirements	<ul style="list-style-type: none"> • Documentation and preparation of reports relating to organizational activities (PvPI) in respect of personnel (staffing, recruitment, training, grievances, performance evaluations etc) • Assisting in compilation and organizing the performance reports of employees under PvPI. • Assisting and monitoring the attendance of the employees of PvPI including employees working in NCC & AMCs on monthly basis. • Maintaining and updating the data base of the newly engaged personnel within NCC and AMCs. • Maintaining performance appraisal system of the employees from time to time using the assessment information for the purpose of trainings, promotions and incentives etc.

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Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		27/10/2016
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6.	Period of Engagement	<ul style="list-style-type: none"> The engagement shall be initially for a period of one year which can be further extended/curtailed basing on performance.
7.	Method of recruitment	<ul style="list-style-type: none"> Direct Recruitment
8.	Selection Committee	<ul style="list-style-type: none"> Constituted by Secretary-cum Scientific Director

5.12.3 Recruitment rules for IT Associate Post

1.	Name of the Post	IT Associate (Contractual)
2.	Salary	As per norms
3.	Age limit	Not exceeding 30 years
4.	Educational and other qualifications required	<p>Essential: B Tech in Computer Science & Information Technology. Preferably one year experience in Pharmacovigilance (PV).</p> <ul style="list-style-type: none"> Knowledge in C++, C, .net, HTML, PHP, My SQL, JAVA will be preferred.
5.	Job requirements	<ul style="list-style-type: none"> Handling of the issues related to ADR e-reporting. Development and maintenance of IT tools related to PV such as e-reporting, Mobile App. Development of innovative IT technology Developing indigenous software for ADR reporting. Setting up new user's accounts and profiles and dealing with password issues of PV software. Troubleshooting system and network problems with other activities as assigned by competent authority time to time.
6.	Period of Engagement	The engagement shall be initially for a period of one year on performance which can be further

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
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		extended/curtailed based on the performance.
7.	Method of recruitment	<ul style="list-style-type: none"> Direct Recruitment
8.	Selection Committee	<ul style="list-style-type: none"> Constituted by Secretary-cum Scientific Director

5.12.4 Recruitment rules for Biostatistician Post

1.	Name of the Post	Biostatistician (Contractual)
2.	Salary	As per norms
3.	Age limit	Not exceeding 30 years
4.	Educational and other qualification required	<p>Essential: Postgraduate degree in Bio-Statistics/Statistics.</p> <p>Desirable: Knowledge of computer software/ applications (SAS, SPSS, STATA, MS-Office, etc.).</p> <p>Experience:</p> <ul style="list-style-type: none"> One year relevant work experience in handling Clinical/ Pharmacovigilance data will be preferred.
5.	Job Requirements	<ul style="list-style-type: none"> Designing and implementing data gathering. Evaluating the statistical methods and procedures used to obtain data in order to ensure validity, applicability, efficiency, and accuracy. Developing data collection and signal detection process. Interpretation of results, data collection. Processing large amounts of data for statistical modelling including information in the form of graphs, charts and tables and graphic analysis using statistics.

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
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		<ul style="list-style-type: none"> Presentation of data to assist in coordinating and monitoring various activities of the programme.
6.	Period of Engagement	The engagement shall be initially for a period of one year which can be further extended /curtailed based on the performance.
7.	Method of recruitment	<ul style="list-style-type: none"> Direct Recruitment
8.	Selection Committee	<ul style="list-style-type: none"> Constituted by Secretary-cum Scientific Director

5.12.5 Recruitment rules for Pharmacovigilance Officer Post

1.	Name of the Post	Pharmacovigilance Officer (Contractual)
2.	Salary	As per norms
3.	Age Limit	Preferably below 40 years
3.	Educational and other qualification required	<p>Essential: MBBS/ BDS/M. Pharm. /Pharm. D from a recognised University.</p> <p>Experience: Five years experience in Pharmacovigilance with good management and communication skills.</p> <p>Desirable:</p> <ul style="list-style-type: none"> Doctorate in Pharmaceutical Sciences and Knowledge of Computer Application will be preferred.
5	Management & Communication Skill	<ul style="list-style-type: none"> Good communication and interpersonal skills. Ability to work effectively with people with different back grounds. Ability to work independently as well as in a team. <p>Highly motivated with a strong desire to protect health and safety of the people.</p>

	Name	Designation	Signature	Date
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Reviewed by	Dr Pawan K. Saini	S.O.	<i>MS</i>	27/10/2016
Approved by	Dr. V. Kalai Selvan	PSO	<i>U</i>	28/10/2016



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6.	Job Requirements	<p>a. Overall responsible for operational technical and managerial matters of ADR Centres under PvPI in their respective zones/states.</p> <p>b. Critically assess the PSURs with supportive help from NCC and AMCs to determine the risk-benefit of medicinal products under question.</p> <p>c. Screening of PSUR for Pharmacovigilance activities.</p> <p>d. Coordinating with state/ district wise focal personals of National Health Programmes such as UIP, RNTCP, and NACP etc. to monitor the adverse events of vaccines / drugs.</p> <p>e. Monitoring the working of TAs appointed in AMCs in their respective zones/ states.</p> <p>f. Strengthening of PvPI concept to reach to the urban and rural community of their respective zone/ states by enrolling more number of AMCs into PvPI and promoting rational use of medicines in Village/Taluka, District, Mandal and State level of their respective zones.</p> <p>g. Daily progress should be communicated to National Coordination Centre and concerned officer of CDSCO Zonal Office.</p> <p>h. Ensuring Training/sensitization/ feed back to clinicians/pharmacists/ para medical staff etc.</p> <p>i. Other activities as assigned from time to time by the competent authority.</p>
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	Name	Designation	Signature	Date
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Reviewed by	Dr. Pawan K. Saini	S.O	<i>[Signature]</i>	27/10/2016
Approved by	Dr. V. Kalai Selvan	P.S.O	<i>[Signature]</i>	28/10/2016

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7.	Period of Engagement	The engagement shall be initially for a period of one year which can be further extended/ curtailed based on the performance.
8.	Method of recruitment	<ul style="list-style-type: none"> • Direct Recruitment
9.	Selection Committee	<ul style="list-style-type: none"> • Constituted by Secretary-cum Scientific Director

5.12.6 Recruitment rules for Senior Pharmacovigilance Associate Post

1.	Name of the Post	Senior Pharmacovigilance Associate (Contractual)
2.	Salary	As per norms
3.	Age Limit	Not exceeding 35 years
4.	Educational and Other Qualification Required	<p>Essential: MBBS/ BDS/M. Pharm. /Pharm. D from a recognised University.</p> <p>Experience: Three years experience in relevant field, out of which two years experience exclusively in the field of Pharmacovigilance.</p> <p>Desirable:</p> <ul style="list-style-type: none"> • Knowledge of Computer Application will be preferred.
5.	Management & Communication Skill	<ul style="list-style-type: none"> • Good communication and interpersonal skills. • Ability to work effectively with people with different back grounds. • Ability to work independently as well as in a team.
6.	Job Requirements	<p>a) Reviewing analysis of PSURs and follow up action with stakeholders.</p> <p>b) Benefit-risk evaluation of Medicinal Products available in Indian Market.</p> <p>c) To supervise the assigned work and assist the senior officials.</p>

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
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		d) Assisting in quality review and signal review of ICSRs. e) To provide Vigiflow hands on training to the newly engaged personnel in PvPI. f) Assisting the NCC for document control. g) Any other work as assigned by competent authority from time to time.
7.	Period of Engagement	The engagement shall be initially for a period of one year which can be further extended/curtailed based on the performance.
8.	Method of recruitment	Direct Recruitment
9.	Selection Committee	Constituted by Secretary-cum Scientific Director

5.12.7 Recruitment rules for Data Entry Operator Post

1.	Name of the Post	Data Entry Operator (Contractual)
2.	Salary	As per norms
3.	Educational and Other Qualification Required	Essential: <ul style="list-style-type: none"> Graduate in any discipline. Knowledge of Computer Application
4.	Age Limit	Not exceeding 25 years
5.	Job Requirements	<ul style="list-style-type: none"> Assisting in compiling and preparing the training module for training. Assisting in drafting of resource materials of PvPI. Dispatch of printed as well as E-version of resource materials of PvPI in various regions. Assisting in all procurement, financial and administrative work related to PvPI.

	Name	Designation	Signature	Date
Prepared by	ANUSHA.R	HR ASSOCIATE		26/10/2016
Reviewed by	Dr. Bawan R. Saini	S.O.		27/10/2016
Approved by	Dr. V. Kalaiselvan	PSO		28/10/2016

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		<ul style="list-style-type: none"> Assisting in preparation of documents related to QA/ QC. Assisting in preparation of all PvPI related documents, control, maintenance and archival. Follow up with the Cash division for all finance related matters of AMCs, RTCs, NCC and others. Other activities as assigned by the competent authority from time to time
6.	Period of Engagement	<ul style="list-style-type: none"> The engagement shall be initially for a period of one year which can be further extended/curtailed based on the performance.
7.	Method of recruitment	<ul style="list-style-type: none"> Direct Recruitment
8.	Selection Committee	<ul style="list-style-type: none"> Constituted by Secretary-cum Scientific Director

5.12.8 Recruitment rules for Multi Tasking Staff Post

1.	Name of the Post	Multi Tasking Staff (Contractual)
2.	Salary	As per norms
3.	Age Limit	Preferably below 25 years
4.	Educational and other qualification required	Essential : Higher secondary
5.	Job Requirements	Upkeep of the section; carrying of files and other papers within the building; photocopying, making sets, stapling, spiral bindings, sending of FAX etc.; <ul style="list-style-type: none"> Other non-clerical work in the section; assisting in routine office work like diary, dispatch; Delivering of dak inside and outside

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		27/10/2016
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		<p>of Institute; Opening & closing of rooms, windows, machineries etc.; Some office related work in all respects as per the needs of the section like LCD Projector, Computer, OHP, Audio-Video system as required in Seminar, Conference Hall etc., & all other events inside the institute and other venues where the events would be held.</p> <ul style="list-style-type: none"> Maintenance of files & folders.
6.	Period of Engagement	<ul style="list-style-type: none"> The engagement shall be initially for a period of one year which can be further extended/curtailed based on the performance.
7.	Method of recruitment	<ul style="list-style-type: none"> Direct Recruitment

6.0 SAFETY AND PRECAUTIONS (IF ANY)

All recruitment process shall be accessible by authorised personnel only to maintain confidentiality.

7.0 REFERENCES : In-house

8.0 ABBREVIATIONS

NCC	:	National Coordination Centre
PvPI	:	Pharmacovigilance Programme of India
IPC	:	Indian Pharmacopoeia Commission
SOP	:	Standard Operating Procedure
AMC	:	Adverse Drug Reactions Monitoring Centre
RR	:	Recruitment Rules
HR	:	Human Resource
IT	:	Information Technology
CDSCO	:	Central Drugs Standard Control Organization

9.0 Annexure(s):

Annexure No. I : Application form format No. IPC/PvPI/HR/001-F01

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE	<i>[Signature]</i>	26/10/2016
Reviewed by	Dr. Ranjan K. Saini	SO	<i>[Signature]</i>	27/10/2016
Approved by	Dr. V. Kalaiselvan	PSO	<i>[Signature]</i>	27/10/2016



INDIAN PHARMACOPOEIA COMMISSION
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Annexure-I
APPLICATION FORM

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Format No. IPC/PvPI/HR/001-F01-00

Paste your recent
passport size
photograph

1. Name of the Post Applied for:

2. Full Name of the Candidate:

(In Capitals)

--	--	--	--	--	--

3. Date of Birth: Day Month Year

4. Gender: (Write '1' for Male, '2' for Female)

5. Marital Status:

6. Father's/Husband's Name:

.....

7. Mailing Address (in block letters):

.....

.....

Pin Code:

Tel. No.:

Mobile No.:

Email ID (if any):

8. Nationality:

9. Whether Physical Handicapped? : (Write '1' for Yes, '2' for No)

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		28/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.		29/10/2016
Approved by	Dr. V. Kalaithe	P30		28/10/2016

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10. Community (please tick \checkmark) SC ST OBC GENERAL

11. All Educational/other professional Qualifications/Training Courses etc from 10th Standard Board Examination onwards:

Level	Exam passed/ Degree Trg.	Division/Gra de % of Marks	Year of Passing	Duration of the Degree/ Diploma	Board/ University	Subject	Subject of Specialisation

12. Brief professional experience:

Office/ Instt. Firm	Post held	Part time/ Contract Basis/ Ad- hoc/ regular/ Temp./pmt.	Exact dates to be given (indicate day, month & year)		Total Period (in years)			Scale of pay	Nature of duties
			From	To	Years	Months	Days		

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	MR ASSOCIATE	<i>[Signature]</i>	26/10/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>[Signature]</i>	27/10/2016
Approved by	Dr. V. Kalaiselvan	AG	<i>[Signature]</i>	28/10/2016

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13. Any other relevant information:

.....

14. Details of enclosures: 1)

2)

3)

Declaration:

I hereby declare that all the statements made in the application are true and complete to the best of my knowledge and belief. I understand that action can be taken against me by the Commission, if I am declared by them to be guilty of any type of misconduct mentioned herein. I have informed my Head Office/Department/ Employer, in writing that I am applying for this selection.

Date:

Signature of candidate

Place:

Address:

	Name	Designation	Signature	Date
Prepared by	ANUSHA R	HR ASSOCIATE		26/10/2016
Reviewed by	Dr Pawan K Saini	S.O.		27/10/2016
Approved by	Dr. V. Kalaijehan	DO		28/10/2016