Date: Mon, 13 Dec 2021 14:44:10 +0530
From: "regr" <regr@pu.ac.in>
To: dui@pu.ac.in, deanresearch@pu.ac.in
Subject: Fw: Nominations for fifth Training Course for GLP Inspectors scheduled to be held at New Delhi/ Delhi NCR during February, 2022

---------- Forwarded Message ----------
From: "Dr. Ekta Kapoor" <ekta.kapoor@nic.in>
To: regr@pu.ac.in
Cc: "Virendra S. Dhayal" <vs.dhayal@nic.in>
Sent: Mon, 13 Dec 2021 14:36:21 +0530 (IST)
Subject: Nominations for fifth Training Course for GLP Inspectors scheduled to be held at New Delhi/ Delhi NCR during February, 2022

Dear Sh. Nayyar ,

Greetings from National GLP Compliance Monitoring Authority (NGCMA), DST, New Delhi!!!

National Good Laboratory Practice (GLP) Compliance Monitoring Authority {NGCMA} was established in the Department of Science & Technology (DST), Government of India through the [UTF-8?]Cabinetâ€™s approval in April, 2002 with the objective of providing recognition (GLP certification) to the laboratories/ Test Facilities (TFs), which are involved in conducting safety studies on chemicals in accordance with Organization for Economic co-operation and Development (OECD) Council Norms. It aims to assure the regulatory authorities that the safety data they receive from GLP-certified TFs can be relied upon when making assessments of hazards or risk to man, animal and/or the environment. India is a full adherent to OECD Council Acts related to Mutual Acceptance of Data (MAD) w.e.f. March 3, 2011. As a result, the data generated by the GLP certified TFs in India is acceptable in the 38 OECD member-countries and 7 non-OECD member full adherent to MAD Countries.

Till date, the NGCMA has certified 49 TFs in the country. The TFs are inspected by qualified and trained GLP inspectors and non-compliance with OECD Principles of GLP has serious regulatory implications. Hence, the role of GLP inspectors is very critical.

NGCMA organizes training courses for GLP inspectors periodically. The training and evaluation of GLP inspectors is guided by [UTF-8?]NGCMAâ€™s Document No. GLP-107 titled [UTF-8?]â€œTraining and evaluation of GLP [UTF-8?]inspectorsâ€, which may please be seen at NGCMA website (https://dst.gov.in/ngcma).

It is proposed to organize the fifth training course for GLP Inspectors in February 2022 to train about 30-35 experts as GLP Inspectors in this training course by including nominations from Government departments/ agencies/ public funded institutions. The purpose of organizing the training course is to enlarge the existing pool of GLP Inspectors.

circulate.
14/12/21

It is requested to nominate 1-2 scientists from your organization with requisite qualifications and experience as detailed below for this training course:

Educational Qualification and Experience: [UTF-8?]Masterâ€™s Degree in Science or [UTF-8?]Bachelorâ€™s Degree in Engineering/ Medicine/ Pharmaceutical/ Veterinary Sciences. Minimum five years in relevant field of safety studies/ regulatory function/ basic or regulatory research/ Science & Technology (S&T) management.

The nomination(s) may be sent along with the filled in the biodata format (to be filed by the nominee) attached with this letter. Selection of candidates for this training will be finalized by NGCMA.

During the training, the candidates will also be evaluated. Subsequently, the candidates will become eligible for participation in [UTF-8?]NGCMAâ€™s Inspection process.

The nomination of candidates will imply the willingness of the institution to

spare their services for inspection work on the request of NGCMA. Their services would be required for GLP inspections, at the most once a month, each inspection being of 2-3 days. All their expenses in respect of such inspections will be borne by NGCMA.

The training course would be for a five-day duration and would be fully residential. Travel and stay of the participants will be borne by the NGCMA as per Government of India rules.

The nominations along with filled-in Biodata format should reach NGCMA on the e-mail [mailto:ekta.kapoor@nic.in | ekta.kapoor@nic.in] latest by December 20, 2021.

Kind regards, Ekta

Dr. Ekta Kapoor
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------- End of Forwarded Message -------

Attachment 1: OriginalMsg.htm (23KB) Delete WebDisk 0-1
Type: text/
Encoding: quoted-printable
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Attachment 2: Format for Biodata.pdf (109KB) Delete WebDisk 0-2 a
Type: application/pdf
Encoding: base64
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Biodata of Candidate

1. Name:

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2. Date of Birth:

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3. Date of Superannuation:

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4. Name of the organization:

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5. Designation:

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6. **Contact Details:**
   Address:

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   Phone Nos. .....Mobile: .....

   E-mail: .....

7. Highest Qualification with Subject/ Specialization:

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8. Area(s) of expertise of work (Please tick whichever is applicable)

   a) Physical-chemical Testing
   b) Toxicity Studies
   c) Mutagenicity Studies
   d) Environment Toxicity Studies on Aquatic and Terrestrial Organisms
   e) Study on Behavior in Water, Soil and Air; Bioaccumulation
   f) Residue Studies
   g) Studies on effects on Mesocosms and Natural Ecosystems

h) Analytical and Clinical Chemistry Testing

i) Others (please specify) .....

9. Work Experience (in Years): .....

10. Current Field of work and job responsibilities: .....

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11. Exposure to quality systems (e.g. ISO, NABL, NABH, GLP, GCP, etc.) and Regulatory framework of different test items/ chemicals in India. Please also list training(s) attended (specifically related to Quality Systems/ Regulatory framework):

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12. According to your perceptions/ knowledge, please answer the following:

a) What is the need of GLP in generating data for pre-clinical studies?

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b) Name the regulatory authorities in India responsible for regulation of:

I. Pharmaceuticals: .....

II. Cosmetic Products: .....

III. Medical Devices: .....

IV. Agrochemicals: .....

c) What is the importance of:

I. Having a document control system /Sops in any research environment.

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II. Archiving of research data

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III. Calibration of equipment used in generating safety data.

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(Signature of the Candidate)