Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 69/ 2024

13 -11-1445 H
21 -05-2024

To All:
Drug Stores
Pharmaceutical Consultancy Services Companies
Local Pharmaceutical Industries

After Compliments,

Sub: Procedure to Approve Contract Research Organizations (CROs).

1. Reference to para 3 of article 62 of the Ministerial Decision No. 113/2020 which stipulates that to register a medicinal product, the quality, effectiveness and suitability of the medicines must be proven by passing the necessary tests including the Bioavailability (BA) and Bioequivalence (BE) in accordance with global standards and based on a recent study issued by impartial scientific body that is approved by the Drug Safety Center. And reference to the Ministerial Decision No. 71/2024 dated 5/3/2024 which defined the fee to approve a CRO. It was decided to issue this circular to outline the procedure for submitting applications to approve/ re-approve a Contract Research Organizations (CROs). It is imperative that applicants adhere to these instructions to ensure smooth process.
2. **Application Submission:** Applicants must complete the attached application form accurately and to provide all necessary information. Incomplete forms will not be processed. Completed forms should be submitted to the Section Head of Registration of Human Medicines.
3. **Supporting Documentation:** Along with the application form, applicants must submit all supporting documents mentioned in the form.
4. **Payment of Fees:** applicants must pay the requisite fee (300/OR).
5. **Assessment:** the application and submitted documents will be reviewed by the concerned department. Queries shall be communicated to the applicant for fulfillment.

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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سلطنة عُمان
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رؤية عُمان 2040

6. **Decision Making:** Complete applications will proceed to the Technical Committee of Registration and Pricing (TCR&P) for decision making.
7. **Communication:** Applicants will be notified the outcome of their application.
8. **Site Inspection:** Approval process might require site inspection of the CRO.
9. **Approval:** An approval certificate will be issued for approved CROs. The validity of the approval will be 5 years.

For additional information or assistance regarding the application procedure, please do not hesitate to contact the Section Head of Registration of Human Medicines.

Dr. Mohammed Hamdan Al Rubaie
Director General

سلطنة عمان - وزارة الصحة
مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

Encl: a/a
Cc:

- All Directors in DSC.
- All Section Heads in DG Office

DSC
مركز سلامة الدواء
Drug Safety Center

ISO 9001:2015 CERTIFIED QUALITY MANAGEMENT SYSTEMS

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: **393** Muscat - Postal Code: **100** - Tel: **22357111** - Fax: **22358489**
@DSCPHO Email: **dscpho@moh.gov.om**

Application Form

Request to Approve Contract Research Organization

☐ **New** ☐ **Renewal**

Section 1. Bioequivalence Centre information

▪ Name			
▪ City			
▪ County			
▪ Postal code			
▪ Address			
▪ Telephone number			
▪ Website			
▪ Email address			
▪ Country of Origin approval date			
▪ Approval from Health Authorities	**Health Authorities**	**Approval date**	**Expiry date**
	☐ USFDA		
	☐ WHO		
	☐ Health Canada		
	☐ TGA		
	☐ EMA		
	☐ MHRA		
	☐ Not Applicable		
▪ Approval from other Health Authorities & Date of approval			

Section 2. Activities carried out/ out sourced by the CRO

***Mention the activities that are conducted by the CRO or Outsourced**

2.0.1 Clinical Phase

▪ Bioequivalence centre clinical analysis	☐ CRO ☐ Outsource
▪ Bioequivalence centre biochemistry laboratory	☐ CRO ☐ Outsource
▪ Bioequivalence centre hospital & clinics	☐ CRO ☐ Outsource

2.0.2 Analytical Phase

▪ Bioequivalence centre analytical Assays	☐ CRO ☐ Outsource
▪ Bioequivalence centre pharmacokinetic analysis	☐ CRO ☐ Outsource

2.0.3 Statistical Phase

▪ Bioequivalence centre statistical analysis	☐ CRO ☐ Outsource

2.1 Clinical Phase (Clinic for hospitalization)

▪ Name	
▪ Address	
▪ Telephone number	
▪ Email address	

2.2 Clinical Phase (Clinical Analysis Laboratory)

▪ Name	
▪ Address	
▪ Telephone number	
▪ Email address	

2.3 Analytical Phase (Analytical Assays)

▪ Name	
▪ Address	
▪ Telephone number	
▪ Email address	

2.4 Statistical Phase (Statistical Analysis)

▪ Name	
▪ Address	
▪ Telephone number	
▪ Email address	

Section 3: Other information

▪ Bioequivalence centre total area	
▪ Bioequivalence centre operational capacity	
▪ Bioequivalence centre biochemistry Laboratory total area	

▪ Bioequivalence centre clinical ,analysis laboratory total area	
▪ Bioequivalence centre number of technicians	
▪ Bioequivalence centre area for hospitalization of subjects	
▪ Bioequivalence centre average number of tests	
▪ Bioequivalence centre number of technicians in clinical phase	
▪ Bioequivalence centre number of technicians in analytical phase	
▪ Buildings affiliated to the Bioequivalence centre (If any)	☐ Yes ☐ No Address :

Section 4: Attachments

▪ Bioequivalence centre CRO master file	
▪ Bioequivalence centre license issued by Health Authority	
▪ Bioequivalence centre inspection report issued by country of origin & Health Authorities in which the centre is approved. (Full Inspection Report)	
▪ GLP & GCP certificates	
▪ Last inspection report by MOH, Oman (for renewal application , if available)	