



Department for
Business, Energy
& Industrial Strategy

[REDACTED]
Biopharma Excellence GmbH

Attn: [REDACTED]

By email to: [REDACTED]

Date: 21/12/2020

Our ref: TRN 2569/08/2020 (Ext)

Dear Sirs,

Letter of Variation to extend End Date of contract for the supply of **Technical Regulatory Expert on Vaccines, including** knowledge & experience of MHRA & EMA procedures in vaccine licensing. (Contract Variation).

Following the award of a contract to you for the supply of a Technical Regulatory Expert on Vaccines, to The Department of Business, Energy & Industrial Strategy (BEIS), the following notice of variation changes the end date of the said agreement from the 31st December 2020, to [REDACTED].

There will be otherwise no change to cost, rates or of any other aspect of the overall scope of services as reflected in the original agreement.

The original agreement is provided at Annex 1 and the same Terms and Conditions of Service (DPF31) shall apply which are included at Annex 2.

Liaison

For general liaison your contact will continue to be [REDACTED]

We thank you for your co-operation to date, and look forward to continuing a successful working relationship with you. Please confirm your acceptance of this Variation by signing and returning this letter of variation to [REDACTED] at the soonest opportunity. No other form of acknowledgement will be accepted.

Yours faithfully,

[REDACTED]

[REDACTED]

VTF Commercial Team

Signed for and on behalf of The Department for Business, Energy and Industrial Strategy

Name:

[REDACTED]

Signature:

[REDACTED]

Date: 21/12/2020

We accept the terms set out in this letter and its Annexes, including the Conditions.

Signed for and on behalf of Biopharma Excellence GmbH

Name:

[REDACTED]

Signature:

[REDACTED]

Date: December 22, 2020

Annex 1

Contract for supply of Technical Regulatory Expert on Vaccines, including knowledge & experience of MHRA & EMA procedures in vaccine licensing.



DPF33 Contract
Offer - [REDACTED]

Annex 2

Terms and Conditions of Contract for Services



DPF31 Terms and
Conditions for Service

Annex 3 – Specification of Requirements and Charges

(Please note prices are quoted in Euros)

Criteria Title	Criteria Description	Mandatory, Essential, Desirable Requirement	Weighting	Candidate Response (There is no specific word count but please keep as concise as possible and only include information relevant to the Requirement. Alternatively if the response is covered in the CV/s, you may state 'refer to CV')
Mandatory				
Speed of availability	Must be available at immediate notice (48hrs from notification of assignment)	Mandatory	N/A	Y
Eligibility to work	Must be eligible to work for HMG	Mandatory		Y
Duration	[REDACTED]	Mandatory		Y
CV	Full CV must be provided for candidate assignees	Mandatory		Y
Experience	Must have experience of taking vaccines through regulatory approval	Mandatory		Y
MHRA & EMA	Regulatory expertise including knowledge and experience of both MHRA and EMA procedures to licence a vaccine	Mandatory		Y
Technical Capabilities based on assessment of CV, experience, knowledge & qualifications (Weighting - 60%)				
Advisory-Level Experience	Experience in advising pharmaceutical companies on critical vaccine-related regulatory process – in both clinical and manufacturing areas	Essential	20	Refer to CV
Virology Capability	Key competence and capability in virology, with knowledge and experience of respiratory viral vaccines	Essential	20	
Innovation	Ability to demonstrate innovative thinking in how data can be prepared for regulatory assessment. Demonstrate through examples	Essential	10	
Influence & Collaboration (Regulatory Approval)	Ability to influence vaccine developers and assist them collaboratively in readiness for regulatory assessment. Demonstrate through examples.	Essential	10	
Flexibility/Adaptability of Approach (Weighting - 10%)				
Flexibility & Adaptability	Ability to advise vaccine developers on how they can best prepare their case for regulatory approval, using a flexible examination of the approach they have chosen to enact clinical trials, collect data and prepare during pre-approval. Demonstrate through examples.	Essential	10	Refer to CV
Price Schedule - 30%				
	Dayrate (£) Please include the dayrate (excl. VAT)	N/A	[REDACTED]	
	Total cost based on dayrate for [REDACTED]	N/A		
	Any other costs not included in the above [REDACTED]	N/A		
	Total Price			