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Subject: Coronavirus (COVID-19) update from LGC Drug Development Solutions

As we enter the 3rd national lockdown, I would like to update you in regards to activities at our Fordham and Sandwich sites. Our Drug Development Solutions business has remained open throughout the COVID pandemic and we have no plans for this to change. The measures outlined below are key extensions of those stated in earlier updates. Measures detailed in my previous updates remain in place.

6th January 2021 update

Key LGC staff members will be re-issued a formal letter granting us right of way to both our Fordham and Sandwich facilities. The services performed in our laboratories relate to critical areas of healthcare, security and the economy at this time including:

- analytical support for clinical trials that are critical to the development and testing of new drugs, possibly including future COVID-19 drugs;
- analytical testing of pharmaceutical materials for release to the supply chain e.g. propellant gas (HFA) used in inhalation devices;
- analytical services for the Ministry of Defence;
- analytical services for Police Forces; &
- analytical services in support of the UK Criminal Justice System and the UK Coroners' system.

All our sites comply with government COVID Secure guidelines on social distancing and have introduced measures including:

- A large percentage of staff working from home to reduce the density of people on site at any time;
- Split-shift working to reduce the density of people on site at any time;
- Mandatory wearing of laboratory PPE;
- Mandatory wearing of face coverings communal areas;
- Availability of hand sanitisers throughout the site;
- Minimal 'face-to-face' meetings. Mostly replaced by Skype;
- Limited numbers of people in designated rooms;
- COVID App QR codes displayed at entrances to the buildings;
- 2 metre social distancing wherever practical; &
- Enhanced site cleaning in place including regular sanitisation of contact points such as door handles.



15th April 2020 update

We are working according to regulatory advice from the MHRA to ensure the maintenance of our Quality Management System during this difficult period.

- **Remote Auditing:** enabling sponsor auditors to electronically assess and evaluate LGC policies, procedures and processes to assist the company in
 - a) making its vendor selection or
 - b) approval of continued use.

- **Process (remote auditing):** Prior to audit, we will complete
 - i. an RFI/questionnaire (if requested to do so)
 - ii. agree the scope of audit and agenda
 - iii. provide an audit documentation pack which will include:
 - Regulatory certificates
 - SOP Document Register
 - Validated Systems list
 - Master schedule list (sponsor studies)
 - other documents as requested
 - iv. Skype, the remote audit will take place by Skype, which will enable screen sharing to provide Company overview presentation, Quality System presentation and others where applicable. Interviews with key LGC staff will also be available. Key documents will be shared via file tray or screen sharing.
 - v. Video, a short video of the LGC laboratories will also be available.

We believe the remote audit option is a good alternative approach in the interim, followed by an on-site visit as soon as reasonably possible.

- **Future Planning** If you are experiencing laboratory closures or delays (internal or external partners) please feel free to contact me. If we plan now, by e.g. validating methods, laying down QC's, initiating Long Term Stability Assessments we can ready ourselves in advance of study initiation and a potential surge of activities once the Covid-19 pandemic subsides.

25th March 2020 update

LGC's Chief Scientific Officer has issued key LGC staff members a formal letter granting us right of way to both our Fordham and Sandwich facilities. The services performed in our laboratories relate to critical areas of healthcare, security and the economy at this time including:

- analytical support for clinical trials that are critical to the development and testing of new drugs, possibly including future COVID-19 drugs;
- analytical testing of pharmaceutical materials for release to the supply chain e.g. propellant gas (HFA) used in inhalation devices.
- analytical services for the Ministry of Defence;
- analytical services for Police Forces; &
- analytical services in support of the UK Criminal Justice System and the UK Coroners' system.



16th March 2020 Update - as reported with no new changes:

- ***Business Continuity Plans.*** LGC has a well-developed set of BCDR plans covering all potential risks, and these include specific plans at our Fordham laboratory. This is tested regularly under various scenarios, and was recently tested under a specific COVID-19 scenario to test our readiness and preparations. The test went well and confirmed various aspects of our planning.
- ***Travel restrictions*** have been in place for staff at LGC for some time to reduce the risk of transmission, and stocks of relevant precautionary equipment (sanitizer, masks, gloves, wipes etc.) have been acquired to allow operations to continue safely.
- ***First aiders have been trained*** and provided with additional PPE to allow the safe isolation and reading of temperatures if required.
- ***We have now closed our site to visitors for all but essential maintenance and critical reasons.*** This includes the suspension of external audits, but we would be able to offer paper based audits and virtual interviews if these are necessary. Our QA team should be contacted if this needs to be arranged.
- ***We have implemented extensive working-from-home arrangements, and split-shift working schedules*** to reduce the number of employees on the site at any one time and improve our business resilience, and reallocation of work to allow for school closures affecting staff etc. The actions include expanded IT resource and infrastructure to maintain remote access to data and reporting systems. The split-shift arrangements will mean that some staff will be contactable at different times of the working day, but the same project contacts will still be contactable in the same way (phone, email, etc) and these details will be communicated to the relevant project leads separately.
- ***Priority is being directed to maintaining the delivery of sample analysis data and reports*** to customers over other non-time critical activities. We do not plan to close our site, but are able to operate effectively with a reduced number of staff on the site.
- ***LGC have made flexible paid days available to staff*** to support them through this difficult time and allow them to take care of their family as well as work.
- ***We have raised a Quality Change Control to allow greater use of the remote approval of documents by email instead of wet ink signature*** and other potential deviations from normal Quality Management procedures. This will help to alleviate bottlenecks due to access to specific individuals or systems.
- ***Laboratory Supplies and Consumables:*** Prior to the COVID-19 outbreak we were already in an *advanced state of preparedness in relation to supplies and laboratory consumables*, as this has been the focus of a sustained project for possible **Brexit scenarios**. We hold additional stock of key items and have a range of alternative suppliers and supply options in place to sustain the business over an extended period of disruption.
- We are ***monitoring the advice and planning by UK government and WHO closely***, and there are no restrictions or expectations regarding the movement of goods or samples. LGC routinely receives and handles human blood and other tissue samples and is fully equipped to deal with the risk of blood borne pathogens. We work closely with couriers transporting samples to Fordham and will continue to do so. All our laboratories operate to the required Containment Level 2 to be able to control the risk from this type of virus.



One thing I should stress is that at this time, there has been no disruption to our services whatsoever.

All our plans continue to develop and I will be happy to provide future information over the up and coming weeks. If you have any questions, just ask.

I wish you, your family and colleagues all the very best during these challenging times.

Kind regards,

A handwritten signature in black ink, appearing to be 'Michael van der Merwe', written over a faint horizontal line.

Michael van der Merwe
Commercial Director
Health Science and Innovation