Extractables Test Strategy
(For External Distribution)

13 July 2020
Revision 03

Section 1: Background

Saint-Gobain has maintained an extractables testing program to support our customers since 2015 with some alignment to the “Standardized Extractables Testing Protocol for Single Use Systems in Biomanufacturing” published in Pharmaceutical Engineering, November / December 2014, volume 34, No 6. The program has included the following parameters used to produce the extractable profiles for our products:

- Solvents: 70% EtOH and DI Water
- Temperature: 70°C
- Duration: 24 hours
- Process Conditions: post-gamma irradiation and autoclave (as applicable based on the product’s intended use)

Saint-Gobain recognizes the parameters used to evaluate our products to date have not been fully aligned with the BPOG protocol nor the upcoming USP <665> requirements. Additionally, they may not provide a thorough panel of information required by our end-users for evaluating the toxicological safety of their finished goods (e.g. drug product). To strive to meet the needs of the market, Saint-Gobain has provided herein our revised approach to performing a comprehensive extractables analysis. The Saint-Gobain approach described in this strategy includes:

- grouping products into the product families,
- solvent selection using the BPOG protocol, planned revisions to the current BPOG protocol outlined in the Biophorum extractables data review output presentation dated October 2019 and upcoming USP <665> as a guide,
- timelines for publication of each product family’s extractable report, and
- change control commitment as it relates to extractable testing and Saint-Gobain’s position on a continuous extractable profile monitoring program
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### Section 3: Scope and Rationale

#### Table 1: Scope / Product Family Rationales / Daisy Chain Strategy

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<th>Function in Single Use Systems</th>
<th>Part Numbers In Scope</th>
<th>Extractable Report Reference</th>
<th>Rationale for Extractable Report Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-Flex® 001</td>
<td>Extruded Tubing Overmolding</td>
<td>R70-001-000 001-XXX-X 001-XXX-XS 001-XXX-XM X = numeric character S= spool M = mini-spool</td>
<td>C-Flex® 072</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072 and C-Flex® 001, it has been concluded that the extractable profile for C-Flex® 072 can rationally be used to support Single Use Systems (SUS) containing C-Flex® 001. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>C-Flex® 003</td>
<td>Extruded Tubing Overmolding</td>
<td>R70-003-000 003-XXX-X 003-XXX-XS 003-XXX-XM X = numeric character S= spool M = mini-spool</td>
<td>C-Flex® 072</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072 and C-Flex® 003, it has been concluded that the extractable profile for C-Flex® 072 can rationally be used to support Single Use Systems (SUS) containing C-Flex® 003. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>Formulation</td>
<td>Function in Single Use Systems</td>
<td>Part Numbers In Scope</td>
<td>Extractable Report Reference</td>
<td>Rationale for Extractable Report Reference</td>
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<tr>
<td>C-Flex® 050</td>
<td>Extruded Tubing</td>
<td>R70-050-000 050-XXX-X 050-XXX-XS 050-XXX-XM</td>
<td>C-Flex® 082</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 082 and C-Flex® 050, it has been concluded that the extractable profile for C-Flex® 082 can rationally be used to support Single Use Systems (SUS) containing C-Flex® 050. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>C-Flex® 072</td>
<td>Extruded Tubing Overmolding Diptube</td>
<td>R70-072-000 072-XXX-X 072-XXX-XS 072-XXX-XM</td>
<td>C-Flex® 072</td>
<td>Each of these three product families will be tested independently. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile per product family. NOTE: Tubing will not have ink on the OD of the tubing. Rationale: 99+% of the SUS assemblies produced do not contain ink on the OD of the tubing. Further, 80+% of the bulk, non-sterile tubing sold to OEMs do not contain ink on the OD of the tubing. As such, only tubing containing no ink will be supported within this testing program.</td>
</tr>
<tr>
<td>C-Flex® 082</td>
<td>Extruded Tubing Overmolding Diptube</td>
<td>R70-082-000 082-XXX-X 082-XXX-XS 082-XXX-XM</td>
<td>C-Flex® 082</td>
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<tr>
<td>C-Flex® 374</td>
<td>Extruded Tubing Overmolding Diptube</td>
<td>R70-374-000 374-XXX-X 374-XXX-XS</td>
<td>C-Flex® 374</td>
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</tr>
<tr>
<td>Formulation</td>
<td>Function in Single Use Systems</td>
<td>Part Numbers In Scope</td>
<td>Extractable Report Reference</td>
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</tr>
<tr>
<td>C-Flex® 376</td>
<td>Extruded Tubing</td>
<td>R70-376-000 376-XXX-X</td>
<td>C-Flex® 072 C-Flex® 374</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of C-Flex® 072, C-Flex® 374 and C-Flex® 376, it has been concluded that the extractable profile for C-Flex® 072 and C-Flex® 374 can rationally be combined and used to support Single Use Systems (SUS) containing C-Flex® 376. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>C-Flex® - Continued</td>
<td>Overmolding Diptube</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>STHT-C</td>
<td>Tubing Diptube</td>
<td>Refer to product description on drawing for STHT-C or STHT-65 reference</td>
<td>STHT-C</td>
<td>This product family will be tested. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile.</td>
</tr>
<tr>
<td>STHT-65</td>
<td>Tubing</td>
<td>Refer to product description on drawing for STHT-65 reference</td>
<td>STHT-C</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of STHT-C and STHT-65, it has been concluded that the extractable profile for STHT-C can rationally be used to support Single Use Systems (SUS) containing STHT-65. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>STHT-R</td>
<td>Tubing</td>
<td>Refer to product description on drawing for STHT-R reference</td>
<td>STHT-R</td>
<td>This product family will be tested.</td>
</tr>
<tr>
<td>Formulation</td>
<td>Function in Single Use Systems</td>
<td>Part Numbers In Scope</td>
<td>Extractable Report Reference</td>
<td>Rationale for Extractable Report Reference</td>
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</tr>
<tr>
<td>Ultra-C</td>
<td>Tubing Diptube</td>
<td>Refer to product description on drawing for Ultra-C reference</td>
<td>Ultra-C</td>
<td>This product family will be tested. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile.</td>
</tr>
<tr>
<td>Ultra 65</td>
<td>Tubing</td>
<td>Refer to product description on drawing for Ultra-65 reference</td>
<td>Ultra-C</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of Ultra-C and Ultra-65, it has been concluded that the extractable profile for Ultra-C can rationally be used to support Single Use Systems (SUS) containing Ultra-65. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>SPT-60L</td>
<td>Tubing</td>
<td>Refer to product description on drawing for Sani-Tech® SPT-60L</td>
<td>Sani-Tech® SPT-60L</td>
<td>This product family will be tested. NOTE: The drawing or tubing product label MUST specifically indicate the brand Sani-Tech® in order for this extractable report to be applicable. The Pure-Fit® SPT-60L brand is not an equivalent process. The Pure-Fit® SPT-60L brand not in scope will be described on the drawing as SPT-60L or Pure-Fit® SPT-60L.</td>
</tr>
<tr>
<td>Pure-Fit®</td>
<td>Formulation</td>
<td>Function in Single Use Systems</td>
<td>Part Numbers In Scope</td>
<td>Extractable Report Reference</td>
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</tr>
<tr>
<td>SPT-50</td>
<td>Tubing</td>
<td>Refer to product description on drawing for SPT-50</td>
<td>SPT-50</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of SPT-50 and SPT-60, it has been concluded that the extractable profile for SPT-50 can rationally be used to support Single Use Systems (SUS) containing SPT-50 and SPT-60. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>SPT-60</td>
<td>Tubing</td>
<td>Refer to product description on drawing for SPT-60</td>
<td>SPT-50</td>
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</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Formulation</th>
<th>Function in Single Use Systems</th>
<th>Part Numbers In Scope</th>
<th>Extractable Report Reference</th>
<th>Rationale for Extractable Report Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tygon® 3350</td>
<td>Tubing Diptube</td>
<td>ABWXXXXXX X = numeric character</td>
<td>Tygon® 3350</td>
<td>This product family will be tested. Since the tubing functions as a diptube, it will be submerged in the solvents to generate the extractable profile.</td>
</tr>
<tr>
<td>Tygon® 3370IB</td>
<td>Tubing</td>
<td>AHJXXXXXX X = numeric character</td>
<td>Tygon® 3350 STHT-R</td>
<td>After considering the compositions, relative proportions, sourcing of the raw materials and the end use configurations of Tygon 3370IB, Tygon® 3350 and STHT-R, it has been concluded that the extractable profile for Tygon® 3350 and STHT-R can be combined to represent the worst case extractable profile to support Single Use Systems (SUS) containing Tygon® 3370IB. The detailed rationale contains proprietary information about the formulation. Some redaction may be required prior to providing the rationale for review during an onsite audit.</td>
</tr>
<tr>
<td>PharmaFluor® FEP</td>
<td>Tubing</td>
<td>PCAMGXXXXXX PH100XXXXXX PHFE6XXXXXX PH6303XXXXX X = numeric character 7 to 13 characters in length</td>
<td>PharmaFluor® FEP</td>
<td>Product testing has been placed on hold pending FDA acceptance of placing FEP on the GRAS list.</td>
</tr>
<tr>
<td>Formulation</td>
<td>Function in Single Use Systems</td>
<td>Part Numbers In Scope</td>
<td>Extractable Report Reference</td>
<td>Rationale for Extractable Report Reference</td>
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<td>---------------------------------------------</td>
</tr>
<tr>
<td>PharMed®</td>
<td>Tubing</td>
<td>AY2XXXXX X = numeric character</td>
<td>PharMed® BPT</td>
<td>This product family will be tested.</td>
</tr>
<tr>
<td>PharmaPure®</td>
<td>Tubing</td>
<td>AL2XXXXX X = numeric character</td>
<td>PharmaPure®</td>
<td>This product family will be tested.</td>
</tr>
<tr>
<td>VueLife® Bags (All sizes)</td>
<td>Cell Therapy Bag Gene Therapy Bag Bioprocess Bag Cold Storage Bag</td>
<td>VueLife® Bags</td>
<td>VueLife® AC Bags</td>
<td>The VueLife AC Bag has been tested using DSMO, DI water and 70% EtOH each analyzed @ 70°C for 24 hours. A proposal was submitted to the FDA to render FEP as GRAS – ‘Generally Recognized As Safe’. All extractable data completed by Saint-Gobain supports this proposal. Therefore, testing will be suspended for this product family pending the outcome of this proposal.</td>
</tr>
<tr>
<td>VueLife® AC Bags (All sizes)</td>
<td>Cell Therapy Bag Gene Therapy Bag Bioprocess Bag Cold Storage Bag</td>
<td>VueLife® AC Bags</td>
<td></td>
<td></td>
</tr>
<tr>
<td>KryoSure® Bags (All sizes)</td>
<td>Cell Therapy Bag Gene Therapy Bag Bioprocess Bag Cold Storage Bag</td>
<td>KryoSure® Bags</td>
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<tr>
<td>Formulation</td>
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</tr>
<tr>
<td><strong>Bioprocess Bags</strong></td>
<td></td>
<td></td>
<td></td>
<td>This product family will be tested. The bag will be clamped as illustrated by the red line. The ports, tubing and bag will be subjected to the conditions outlined herein. The exact tubing on the bag assembly will be stated in the extractable report.</td>
</tr>
<tr>
<td>Bioprocess Bag (All sizes)</td>
<td>Single Use Bioprocess Bag</td>
<td>K(a)(a)XXXXX K = chamber (a) = alpha character X = numeric character</td>
<td>12 mil Bioprocess Bag</td>
<td></td>
</tr>
<tr>
<td><strong>Sterile Grade Filters</strong></td>
<td></td>
<td></td>
<td></td>
<td>This product family was tested @ 7 Day test interval using the Saint-Gobain test strategy outlined herein. The remaining test interval will be tested as outlined herein to complete the test plan.</td>
</tr>
<tr>
<td>Zero® Filter w/ PES membrane</td>
<td>Sterile Filter</td>
<td>To Be Provided in Future Update</td>
<td>Zero® Filter</td>
<td>The Zero® filter consists of a Z Series filter plus C-Flex® 374 tubing and a vent filter. Therefore, the Z Series filters are covered by the extractable data obtained from testing the Zero® filter family.</td>
</tr>
<tr>
<td>Z Series Filters</td>
<td>Sterile Filter</td>
<td>To Be Provided in Future Update</td>
<td>Zero® Filter</td>
<td></td>
</tr>
<tr>
<td>Formulation</td>
<td>Function in Single Use Systems</td>
<td>Part Numbers In Scope</td>
<td>Extractable Report Reference</td>
<td>Rationale for Extractable Report Reference</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Silicone Overmolding</td>
<td>Overmolding</td>
<td>Refer to product description: Sani-Tech® LIM Sani-Tech® 65 LIM Tygon® 3350 LIM Tygon® 3370 LIM Ultra LIM Ultra 65 LIM PC Silicone ST50 LSR PC Silicone ST65 LSR PC Silicone TYG50 LSR PC Silicone ULT50 LSR PC Silicone ULT65 LSR PC Silicone TYG70 LSR</td>
<td>LIMs/LSR Soup</td>
<td>All Liquid Injected Materials (LIMs) are liquid silicone rubbers (LSR) used to overmold single use assemblies. There are two main grades of LSR materials each of which are purchased at durometers ranging from 50 to 70. As such, the worst case scenario of each LSR grade is the lowest durometer LSR which contains the least amount of additives. To cover the entire range of LSR materials used to manufacture silicone overmolds, the two main LSR materials at 50 durometer will be converted into multi-leg T-reducers where the drop will be plugged with the same LSR material and allow enough space to clamp the ends when performing the extraction. The extractable profile for all silicone overmold materials listed will be the sum of the two LSR materials.</td>
</tr>
<tr>
<td>Formulation</td>
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</table>
| Smooth Inner Bore (SIB) Connectors | Tubing Connector              | PF(A)XXXXPVDFAF (A) = style (e.g. T, cross, etc.) XXX = Size in inches | PVDF-SUS Components             | A PVDF soup will be created to obtain the extractable profile of SUS components manufactured from PVDF. The soup will consist of the following:  
  - PVDF used to mold Pure-Fit® SIB connectors  
  - PVDF used to mold Sani-Tech® Rigid  
  - PVDF used to mold all components constituting the Pure-Fit® Sterile Connector with the exception of the silicone valve. As the PVDF molded components create the fluid contact path, the silicone valve is considered out of scope for extractable testing. |
<p>| Sani-Tech® Rigid Connector  | Tubing Connector              | KXXXXXX-XXX “K” or “T” followed by 5 to 6 alpha or numeric characters then a dash followed by 3 to 4 alpha or numeric characters. KXXXXX “K” or “T” followed by 5 to 7 alpha or numeric characters. | PVDF-SUS Components             |                                                                                                                                                                                                                                                                     |
| Pure-Fit® Sterile Connector | Sterile Connector             | PFSC250-XXX PFSC375-XXX PFSC500-XXX PFSC750-XXX PFSC1000-XXX Where XXX = IHM, OHM or CAM | PVDF-SUS Components             |                                                                                                                                                                                                                                                                     |</p>
<table>
<thead>
<tr>
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<th>Extractable Report Reference</th>
<th>Rationale for Extractable Report Reference</th>
</tr>
</thead>
</table>
| Smooth Inner Bore (SIB) Connectors | Tubing Connector | PF(A)XXXPPAF (A) = style (e.g. T, cross, etc.) XXX = Size in inches | PP-SUS Components | A polypropylene soup will be created to obtain the extractable profile of SUS components manufactured from polypropylene. The soup will consist of the following:  
- Polypropylene used in Clearwater assemblies to manufacture diptubes.  
- Polypropylene used to mold SIB-PP connectors @ Traverse City  
- Polypropylene used to overmold assemblies in Clearwater  
- Polypropylene used to mold Sani-Tech® Rigid connectors in Garden Grove |
| Sani-Tech® Rigid Connectors | Sani-Tech® Rigid Connectors | KXXXXX-XXX “K” or “T” followed by 5 to 6 alpha or numeric characters then a dash followed by 3 to 4 alpha or numeric characters. KXXXXX “K” or “T” followed by 5 to 7 alpha or numeric characters. | PP-SUS Components |  |
| Polypropylene | Overmolding Tubing Diptube | R80-106-000, 30-10008, 30-10013, 30-10014, 30-10115, 30-10175, 30-10482, 30-10488, 30-10519 and 30-10709 |  |  |
NOT IN SCOPE:
Saint-Gobain previously published a BPOG communication dated December 21, 2017. With this communication, it outlined all product families within scope of BPOG testing. Saint-Gobain has since updated its BPOG test strategy and will not actively promote the following products for new Single Use Systems that require extractable data:

- C-Flex® 082 braided tubing
- SaniPure® BDF Tubing
- Pure-Fit® SPT-60L Tubing

Since publishing this test strategy (Revision 0), an additional product is being added to the NOT IN SCOPE section that was previously published as IN SCOPE: Pure-Fit® SPT-60L tubing has been replaced by Sani-Tech® SPT-60L tubing as being IN SCOPE. The Sani-Tech® SPT-60L tubing is produced using a unique manufacturing process not shared with the Pure-Fit® SPT-60L tubing. As a result, the Pure-Fit® SPT-60L tubing is not equivalent to the Sani-Tech® SPT-60L tubing. As such, the Sani-Tech® SPT-60L tubing has been added to the ‘In Scope’ section above. The Pure-Fit® SPT-60L tubing has been added to this section as not in scope.

Therefore, no additional extractable testing will be performed on these product families in the future. The current use of these product families has been substantiated using the historical extractable data on file and summarized in Table 2.
Table 2: Extractable Data for Products NOT IN SCOPE*

<table>
<thead>
<tr>
<th>Product</th>
<th>70% EtOH @70°C for 24 hours</th>
<th>DI Water @ 70°C for 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gamma Irradiated</td>
<td>Autoclave Conditions</td>
</tr>
<tr>
<td>C-Flex® 082 Braided Tubing</td>
<td>√</td>
<td>Not Performed</td>
</tr>
<tr>
<td>SaniPure® BDF Tubing</td>
<td>Not Performed</td>
<td>√</td>
</tr>
<tr>
<td>Pure-Fit® SPT-60L Tubing</td>
<td>√</td>
<td>Not Performed</td>
</tr>
</tbody>
</table>

*Extractable test conditions do not follow recommendations within the BPOG protocol or the upcoming USP <665>. Summary of extractable test conditions and results can be made available upon request.
Section 4: Saint-Gobain Test Strategy Executive Summary

2019 / 2020 Test Plan:
- One unique lot (2\textsuperscript{nd} unique lot is discussed under Ongoing Surveillance section below)
- 3 solvents (DI water, low pH and high pH)
- BPOG protocol test intervals for bags, filters, connectors identified herein
- Tubing commonly assembled to the storage bag will undergo the 70 days @ 40°C time point. One extractable study contained C-Flex\textsuperscript{®} 374 on the Saint-Gobain storage bag. A 2\textsuperscript{nd} study will be conducted with Sani-Tech\textsuperscript{®} STHT-C, Sani-Tech\textsuperscript{®} Ultra-C, Pure-Fit\textsuperscript{®} SPT-50 and Sani-Tech\textsuperscript{®} SPT-60L in conjunction with the Saint-Gobain storage bag.
- Post treatment conditions based on intended use per Saint-Gobain data sheets

2020 / 2021 Test Plan:
- One unique lot (2\textsuperscript{nd} unique lot is discussed under Ongoing Surveillance section below)
- 1 solvent (50\% EtOH)
- BPOG test intervals for bags, filters, connectors identified herein
- Tubing commonly assembled to the storage bag will undergo the 70 days @ 40°C time point. One extractable study contained C-Flex\textsuperscript{®} 374 on the Saint-Gobain storage bag. A 2\textsuperscript{nd} study will be conducted with Sani-Tech\textsuperscript{®} STHT-C, Sani-Tech\textsuperscript{®} Ultra-C, Pure-Fit\textsuperscript{®} SPT-50 and Sani-Tech\textsuperscript{®} SPT-60L in conjunction with the Saint-Gobain storage bag.
- Post treatment conditions based on intended use per Saint-Gobain data sheets

Ongoing Surveillance / Testing Program / Change Control Commitment:
- Extractable testing will be conducted as required when change control necessitates repeating the analysis.
- Saint-Gobain is collaborating with Biophorum to determine if age of data will drive repeat analysis and if so, at what frequency.
- Saint-Gobain is also collaborating with Biophorum to provide a scientific rationale or objective evidence as to the value of testing a 2\textsuperscript{nd} lot since it is not a requirement within the upcoming USP <665>.
### TABLE 3: TEST STRATEGY: COVERAGE, POST TREATMENT, TIME INTERVALS, INTENDED USE

<table>
<thead>
<tr>
<th>Product Family</th>
<th>Testing Coverage</th>
<th>Post Treatment Intended Use</th>
<th>Test Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Gamma Test Condition</td>
<td>Autoclave Test Condition</td>
</tr>
<tr>
<td>C-Flex®</td>
<td>C-Flex® 374</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 376</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-Flex® 082</td>
<td>C-Flex® 050</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 051</td>
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</tr>
<tr>
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<td>C-Flex® 082</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-Flex® 072</td>
<td>C-Flex® 001</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 072</td>
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<td></td>
</tr>
<tr>
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<td>C-Flex® 376</td>
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</tr>
<tr>
<td>Silicone Tubing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sani-Tech® STHT-C</td>
<td>STHT-C STHT-65</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>Sani-Tech® Ultra C</td>
<td>Ultra C Ultra 65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure-Fit® SPT-50</td>
<td>SPT-50 SPT-60</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>Sani-Tech® SPT-60L</td>
<td>SPT-60L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sani-Tech® STHT-R</td>
<td>STHT-R Tygon® 3370IB</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>Tygon® 3350</td>
<td>Tygon® 3350</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td></td>
<td>Tygon® 3370IB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testing Coverage</td>
<td>Gamma Test Condition</td>
<td>Autoclave Test Condition</td>
<td>24h @ 40°C</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------</td>
<td>--------------------------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>TPE Tubing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PharMed® BPT</td>
<td>PharMed®</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>PhamaPure®</td>
<td>PharmaPure®</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td><strong>FEP Tubing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmafluor® FEP</td>
<td>Pharmafluor® FEP</td>
<td>Not Intended Use</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td><strong>Storage Bags</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bioprocess Bags (Plymouth)</td>
<td>All sizes</td>
<td>40 – 55 kGy</td>
<td>Not Intended Use</td>
</tr>
<tr>
<td><strong>Silicone Overmolds</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIM #1 overmold</td>
<td>LIM #1 overmold w/n LIMs soup</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>LIM #2 Overmold</td>
<td>LIM #2 Overmold w/n LIMs soup</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>Product Family</td>
<td>Testing Coverage</td>
<td>Gamma Test Condition</td>
<td>Autoclave Test Condition</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------------------</td>
<td>----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Connectors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure-Fit® SIBs @PVDF w/n PVDF Soup</td>
<td>PVDF Connectors Sani-Tech® Rigid Connectors</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>Pure-Fit® SIBs @PP w/n PP Soup</td>
<td>PP Connectors PP Overmolding PP Tubing Sani-Tech® Rigid Diptube</td>
<td>40 – 55 kGy</td>
<td>60 mins @ 125°C</td>
</tr>
<tr>
<td>Filters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zero® Filter</td>
<td>Zero Filter Z Series filters</td>
<td>40 – 55 kGy</td>
<td>Not Intended Use</td>
</tr>
</tbody>
</table>
## TABLE 4: 2019 / 2020 TEST PLAN PER BPOG SOLVENT

<table>
<thead>
<tr>
<th>Product Family</th>
<th>Low pH</th>
<th>High pH(^1)</th>
<th>DI Water(^2)</th>
<th>50% EtOH(^3)</th>
<th>5M NaCl(^4)</th>
<th>1% PS80(^4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-Flex(^\circ) Tubing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>Silicone Tubing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tygon(^\circ) 3350</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>Not Required</td>
<td>Not Required</td>
</tr>
</tbody>
</table>

1. High pH conditions will follow the upcoming USP <665> of pH = 10. Low pH will follow BPOG protocol since interchangeable with USP <665> low pH; pH will be adjusted if needed based on chemical compatibility.
2. Extractable data available @ 70°C for 24 hours. Testing will be performed at 40°C for time intervals outlined in this table.
3. Extractable data available @ 70°C for 24 hours using 70% EtOH and DI water. Testing will be performed using 50% EtOH at 40°C for time intervals outlined in this table.
4. Updated protocol no longer includes these solvents. As such, they have been removed from the remainder of the document.
<table>
<thead>
<tr>
<th>Product Family</th>
<th>Low pH&lt;sup&gt;1&lt;/sup&gt;</th>
<th>High pH&lt;sup&gt;1&lt;/sup&gt;</th>
<th>DI Water&lt;sup&gt;2&lt;/sup&gt;</th>
<th>50% EtOH&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TPE Tubing</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Silicone Overmolds</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIM #1 overmold w/n LIMs Soup</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
</tr>
<tr>
<td>LIM #2 Overmold w/n LIMs Soup</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
</tr>
<tr>
<td><strong>Connectors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure-Fit® PFSIBs w/n PVDF Soup</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
<td>In Scope (2020)</td>
</tr>
</tbody>
</table>

1 High pH conditions will follow the upcoming USP <665> of pH = 10. Low pH will follow BPOG protocol since interchangeable with USP <665> low pH; pH will be adjusted if needed based on chemical compatibility.
2 Extractable data available @ 70°C for 24 hours. Testing will be performed at 40°C for the time intervals outlined in this table.
3 Extractable data available @ 70°C for 24 hours using 70% EtOH and DI water. Testing will be performed using 50% EtOH at 40°C.
<table>
<thead>
<tr>
<th>Product Family</th>
<th>Low pH(^1)</th>
<th>High pH(^1)</th>
<th>DI Water(^2)</th>
<th>50% EtOH(^3)</th>
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<tbody>
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<td>Filters</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zero(^\circ) Filter</td>
<td>In Scope (2020)(^4)</td>
<td>In Scope (2020)(^4)</td>
<td>In Scope (2020)(^4)</td>
<td>In Scope (2020)(^4)</td>
</tr>
<tr>
<td>Storage Bags</td>
<td></td>
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</tr>
</tbody>
</table>

1 High pH conditions will follow the upcoming USP <665> of pH = 10; Low pH will follow BPOG protocol since interchangeable with USP <665> low pH; pH will be adjusted if needed based on chemical compatibility.
2 Extractable data available @ 70°C for 24 hours. Testing will be performed at 40°C.
3 Extractable data available @ 70°C for 24 hours using 70% EtOH and DI water. Testing will be performed using 50% EtOH at 40°C.
4 Full BPOG testing per the 2014 protocol has been completed @ 7day test interval. The remaining one test interval will be completed in 2021 following the test strategy outlined herein.
### Section 6: Timelines

**Table 5: Timeline for Extractables Test Report Publications per 2019 / 2020 Test Plan (Aqueous Solvents)**

<table>
<thead>
<tr>
<th>Group</th>
<th>Extractable Data Source</th>
<th>Publication Date (EOM = End of Month)</th>
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<tr>
<td></td>
<td><strong>Group 1</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 mil Bioprocess Bag (Plymouth Bag)</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® STHT-C Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® STHT-R Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 374 Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® Ultra C Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 374 Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 374 Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® STHT-R Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® Ultra C Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 374 Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® Ultra C Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>PharmaPure® Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 082 Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>PharmaFluor® FEP Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Pure-Fit® SPT-50 Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 072 Tubing</td>
<td>Gamma – COMPLETE</td>
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<tr>
<td></td>
<td>Tygon® 3350 Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
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<td>LIMs/LSR Soup</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>PP Soup</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>PharMed® BPT Tubing</td>
<td>Gamma – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>PharMed® BPT Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>PharMed® BPT Tubing</td>
<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Group 4</td>
<td></td>
</tr>
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<td></td>
<td>PVDF Soup</td>
<td>Gamma - COMPLETE</td>
</tr>
<tr>
<td></td>
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<td>Gamma (1 day time point) – TBD</td>
</tr>
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<td>(7 day time point already available at our website)</td>
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<td>Gamma – Mar 2021</td>
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<tr>
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<td>Sani-Tech® SPT-60L Tubing</td>
<td>Autoclave – Mar 2021</td>
</tr>
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<td>Group</td>
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<td>Publication Date (EOM)</td>
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<tr>
<td></td>
<td>12 mil Bioprocess Bag</td>
<td>Gamma (T1 and T21) -</td>
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<td>(Plymouth Bag)</td>
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<td>Gamma (T70) – August 2020</td>
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<tr>
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<td>Sani-Tech® STHT-C Tubing</td>
<td>Gamma – COMPLETE</td>
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<tr>
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<td>Autoclave – COMPLETE</td>
</tr>
<tr>
<td></td>
<td>Tygon® 3350 Tubing</td>
<td>Gamma – Mar 2021</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autoclave – Mar 2021</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 374 Tubing</td>
<td>Gamma – July 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autoclave – August 2020</td>
</tr>
<tr>
<td></td>
<td>C-Flex® 082 Tubing</td>
<td>Gamma – August 2020</td>
</tr>
<tr>
<td></td>
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<td>Autoclave – August 2020</td>
</tr>
<tr>
<td>Group 6</td>
<td>Sani-Tech® STHT-R Tubing</td>
<td>Gamma – September 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autoclave – September 2020</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® Ultra C Tubing</td>
<td>Gamma – April 2021</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autoclave – April 2021</td>
</tr>
<tr>
<td></td>
<td>PharMed® BPT Tubing</td>
<td>Gamma – April 2021</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autoclave – May 2021</td>
</tr>
<tr>
<td></td>
<td>PharmaPure® Tubing</td>
<td>Gamma – May 2021</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Autoclave – May 2021</td>
</tr>
<tr>
<td>Group 7</td>
<td>C-Flex® 072 Tubing</td>
<td>Gamma – June 2021</td>
</tr>
<tr>
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<td></td>
<td>Autoclave – June 2021</td>
</tr>
<tr>
<td></td>
<td>Sani-Tech® SPT-60L Tubing</td>
<td>Gamma – March 2021</td>
</tr>
<tr>
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<td></td>
<td>Autoclave – March 2021</td>
</tr>
<tr>
<td></td>
<td>PP Soup</td>
<td>TBD</td>
</tr>
<tr>
<td></td>
<td>LIMs Soup</td>
<td>TBD</td>
</tr>
<tr>
<td>Group 8</td>
<td>PharmaFluor® FEP Tubing</td>
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</tr>
<tr>
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<td>PVDF Soup</td>
<td>TBD</td>
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### Section 7: Change History and Approvals

#### 7.1 Revision Information

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<th>Revision Date</th>
<th>Page(s) Affected</th>
<th>Revision Description</th>
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<tr>
<td>0</td>
<td>26 April 2019</td>
<td>All</td>
<td>Original Issue</td>
</tr>
<tr>
<td>1</td>
<td>01 Nov 2019</td>
<td>1, 2, 6-26</td>
<td>Removed FEP cell / gene therapy bags out of testing scope due to pending review of proposal to FDA to accept FEP film as GRAAS. Removed requirement to repeat testing based on age of data solely. Removed requirement to test 2nd lot. Replaced with statement to collaborate with BPOG on both topics to determine if data expires and whether 2nd lot testing is required. Updated tables to reflect which tubing is undergoing 70d test interval as part of the bioprocess bag. Added External Distribution to the title page. Corrected reference to the extractable protocol. Remove PS80 and 5M NaCl as solvents. Removed time zero interval. Added PFSC to be in scope as part of PVDF Soup. Separated SPT-50 and SPT-60 into its own test family. Added Pure-Fit® SPT-60L to the Out of Scope Section. Added Sani-Tech® SPT-60L to the In Scope section. Adjusted test schedule and report due dates. Updated gamma range target. Fixed time points required for connectors. Added part numbers for the Sani-Tech® Rigid Connectors and PP Soup. Added more part numbers to the LSR / LIMs Soup. Added 2020 due date for performing 50% EtOH test plan. Updated test strategy for 70 day time point.</td>
</tr>
<tr>
<td>2</td>
<td>20 April 2020</td>
<td>4, 20, 22-24</td>
<td>Update aqueous test plan status. Update the 50% EtOH test plan and include target completion dates for the next year. Add C-Flex® R70-003-000 to the test plan since it is also used in SUS assemblies. Removed R70-051-000 from the test strategy as it not used in any single use systems. Corrected the use of R70-050-000 in single use systems.</td>
</tr>
</tbody>
</table>
Update test completion table to reflect completion of reports year to date and change the Tygon 3350 - 50% EtOH report due dates from July 2020 to March 2021. The samples submitted contained ink. Ink is not present when tubing is converted into a single use assembly. 50% EtOH removed all ink. Testing aborted since not representative.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>13 July 2020</td>
<td>22 – 24</td>
</tr>
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### Approval Signatures

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<thead>
<tr>
<th>Prepared By</th>
<th>Signature / Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genine Dale</td>
<td>Dale, Genine M</td>
</tr>
<tr>
<td>Analytical Services &amp; QC Director, Life Sciences</td>
<td>Digitally signed by Dale, Genine M</td>
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</tbody>
</table>

<table>
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<tr>
<th>Approved By</th>
<th>Signature / Date</th>
</tr>
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<tbody>
<tr>
<td>Polly Hanff</td>
<td>Hanff, Polly</td>
</tr>
<tr>
<td>Global Regulatory Affairs &amp; Quality Director</td>
<td>Digitally signed by Hanff, Polly</td>
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<table>
<thead>
<tr>
<th>Jim Ding</th>
<th>Signature / Date</th>
</tr>
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<tbody>
<tr>
<td>R&amp;D Director, Life Sciences</td>
<td>Digitally signed by Ding, Jian L</td>
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<table>
<thead>
<tr>
<th>Aaron Updegrove</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Marketing Director, Bioprocess Solutions</td>
<td>Digitally signed by Updegrove, Aaron</td>
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