STANDARD OPERATING PROCEDURE

Life Science	SOP	Page 1 of 13

Title: SKLSI Copy Review Committee

Approvals:

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Approver 2 Louis Ferrari *VP, Medical Affairs* Please see last page of this document for the Approval signature and date
Approver 3 Hong Wook Kim *Chief Operating Officer* Please see last page of this document for the Approval signature and date
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Version Number	Description of Changes
1.0	Original Version
2.0	Updates to all areas based on input from Medical, Commercial and Regulatory

1. PURPOSE

The purpose of this Standard Operating Procedure ("SOP") is to establish a process for approving SK Life Science, Inc.'s ("SKLSI") Submitted Material to assure that such Submitted Material is in compliance with the Code of Federal Regulations ("CFR") and other applicable laws, rules, Guidances, and SKLSI policies and procedures. This SOP will also establish a process for escalating matters arising from the Copy Review Committee and submitting "Submitted Materials" to the U.S. Food and Drug Administration ("FDA") Office of Prescription Drug Promotion ("OPDP"), as required.

2. SCOPE

This SOP applies to all SKLSI Personnel involved in the creation, review and approval of Advertising, Promotional Labeling, Scientific and Medical Material, and other material (e.g., Health Economics and Outcomes Research ("HEOR") (a/k/a "FDAMA 114 Material")) related to either a product for which SKLSI is responsible for the creation, dissemination and submission of such material, a disease state for which a marketed SKLSI Product may be used for treatment, or the scientific and medical basis underlying a SKLSI Product. This SOP also applies to help-seeking and disease awareness material even though they are not considered promotional (i.e., under FDA regulations). This SOP does not apply to: (a) annual reports and other investor communications; or, (b) clinical trial documents including those that may require Regulatory and/or Legal review (e.g., advertising material for clinical trial patient recruitment); and (c) press releases.

3. DEFINITIONS

3.1. **Advertising** refers to a type of Submitted Material that appears, for example, in/on: (a) journals, magazines, newspapers and other publications; and, (b) broadcast media (e.g., television, radio, cable and satellite).

3.2. **Annotated** refers to the tagging, highlighting and/or underlining of specific sentences, paragraphs, or sections of documents which are used to substantiate claims or provide quotations (e.g., References) to reflect the specific language that supports the referenced statement. For example, an annotated version of, for example, websites for submission to OPDP reflects the URLs for the hyperlinks.)

3.3. **Approved with Changes** refers to the option that the reviewers select when they approve the piece with the changes that are annotated in Veeva PromoMats (only applicable for Legal and Medical reviews). Provides the option to either see or not see the submission again when revisions have been made. Regulatory reviewers must always approve the submission in its final state.

3.4. **Description** refers to the background information (including, the purpose of the Submitted Material, the intended audience(s), a target date for final approval of the Submitted Material by the CRC, as well as a target date for production or delivery of the Final Submitted Material to the intended audience (i.e., proposed date of first

publication) that is entered into Veeva Vault PromoMats at the same time as the corresponding Submitted Material.

3.5. **Consumers** include patients, caregivers, patient advocacy groups, media/press, investors and all other individuals and groups who are not HCPs.

3.6. **Coordinator** oversees and administers the overall CRC process.

3.7. **Copy Review Committee ("CRC")** is composed of the Sponsor and one member from each of the Legal, Medical and Regulatory Affairs Departments who are responsible for reviewing, modifying and approving (or rejecting) all Submitted Material.

The CRC shall be the term used to refer to the single process utilized for both the Promotional Material Review Committee ("PMRC") and the Medical and Scientific Copy Review Committee ("MRC").

3.8. **Final Submitted Material** refers to Submitted Material in its final form as approved by the Copy Review Committee for publication, distribution, or dissemination.

3.9. **Escalation Committee** refers to the committee comprised of the heads of the Legal, Regulatory and Medical Affairs. When the escalation arises out of a Submitted Material reviewed by the PMRC, the Chief Commercial Officer (CCO) will also be a member of the committee. When the escalation arises out of a Submitted Material reviewed by the MRC, the Chief Medical Officer (CMO) will also be a member of the committee.

3.10. **Healthcare Practitioner ("HCP")** refers to a provider of medical or health services, or any other person or organization that furnishes, bills, influences or is paid for healthcare in the normal course of business. HCPs include MDs, DOs, RNs, NPs, PAs, pharmacists, researchers, investigators, hospital personnel (e.g., members of the Purchasing Department), representatives of managed care organizations (e.g., health maintenance organizations ("HMOs") and pharmacy benefits managers ("PBMs")), and members of P&T and formulary committees.

3.11. **Job Code (Document Number)** refers to the unique code assigned to each piece of Submitted Material. The code will follow a format defined by the classification (e.g., Material vs Medical Material and Promotional vs Non-Promotional). The Job Code indicates the reviewing committee (e.g., MRC, or PMRC), the country where the Submitted Material will be used, the brand name (if applicable, and a sequential number assigned to the piece. The Job Code needs to be on displayed on all printed materials.

3.12. **Medical Review Committee ("MRC")** is the committee that reviews and approves all disease state, scientific, medical, and other Submitted Material (including all Submitted Material to be used by Medical Science Liaisons) whose Sponsor is in the department of SKLSI overseen by the Chief Medical Officer. The MRC is composed of the Sponsor and one member from each of the Legal, Medical, and Regulatory Departments, or their designees.

3.13. **Office of Prescription Drug Promotion ("OPDP")** refers to the part of the FDA that reviews advertising and promotional material to ensure that prescription drug advertising

and promotional materials are truthful, balanced and accurately communicated. Such pieces, along with FDA Form 2253, must be submitted in advance of their initial publication.

3.14. **Prescribing Information (a/k/a "full Prescribing Information," "Package Insert" and "PI")** refers to the FDA-approved labeling of a SKLSI Product, which includes indication(s), adverse events, warnings, precautions, and instructions for use in particular patient populations such as pregnant women, children, etc.; it may also include the Medication Guide and/or Instructions for Use ("IFU").

3.15. **Promotional Labeling** refers to a type of Submitted Material that "accompanies" a drug into interstate commerce but is not necessarily attached to a drug container. Promotional Labeling includes: (a) internet (e.g., websites); (b) videos; (c) telephone communication systems (e.g., IVRs for savings card programs); (d) social media; (e) brochures; (f) booklets: (g) mailed material (including Consumer material); and, (h) reminder communications that display a drug's name but make no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use.

3.16. **Promotional Material Review Committee ("PMRC")** is the committee that reviews and approves all disease state, sales and marketing, and other Submitted Material whose Sponsor is in the part of SKLSI overseen by the Chief Commercial Officer. The PMRC is composed of the Sponsor and one member from each of the Legal, Medical, and Regulatory Departments, or their designees.

3.17. **References** are Annotated authorized (i.e., for which SKLSI has a copyright license) reprints of medical journal articles and other documentation (e.g., PI, Data on File) used to support claims or quotations made in Submitted Material.

3.18. **Retirement Date** is the earlier of: (i) the date approved by CRC for the use of a Final Submitted Material (e.g., the dates of a medical conference); or, (ii) one year from the date on which the Submitted Material was approved by CRC.

3.19. **Reviewers** are the designated representatives of the Legal, Medical and Regulatory Departments who are the members of the CRC who review and approve/reject all Submitted Material.

3.20. **Scientific and Medical Material** is Submitted Material whose Sponsor is from the Medical Department.

3.21. **SKLSI Personnel** includes all SKLSI employees, directors, and officers. SKLSI Personnel also encompasses agents, independent contractors, and co-promotion partners

who interact or do business with Healthcare Practitioners or Consumers on behalf of SKLSI.

3.22. **SKLSI Product** refers to any product for which SKLSI is or will be the New Drug Application ("NDA") holder.

3.23. **Sponsor** means any SKLSI Personnel (e.g., a member of the Sales, Marketing or Medical Departments) seeking approval for Submitted Material.

3.24. **Submitted Material** refers to any item or material that informs, solicits, or makes representations to the general public, HCPs, Consumers, patient advocacy groups, payers, media, financial institutions or any third-party regarding a SKLSI Product, a disease state for which a marketed SKLSI Product may be used for treatment, or SKLSI itself. (Examples of Submitted Material are included in Appendix A.)

3.25. **Third-Party Agency** refers to any third-party (e.g., an advertising agency, medical information agency, media buyer or graphics designer) that SKLSI engages to produce pieces that will become Submitted Material.

3.26. **Veeva Vault PromoMats ("PromoMats")** is the software utilized to track Submitted Materials, Reviewers' notations, and other data related to Submitted Materials.

3.27. **Veeva Vault PromoMats Administrator** shall be a representative from the Regulatory Affairs Department who shall have the sole authority to interact with the PromoMats licensor on all issues arising at SKLSI. Notwithstanding the preceding sentence, said representative may designate another SKLSI Personnel (e.g., a representative of the IT Department) to act in such intermediary capacity, when appropriate.

4. RESPONSIBILITY

4.1. **Sponsor**

4.1.1. Sponsor is responsible for ownership of a piece. Although SKLSI may engage a Third-Party Agency for some roles, the Sponsor shall at all times be responsible for the Submitted Material.

4.1.2. Sponsor is responsible for the creation, initial review, and distribution of Submitted Material to Coordinator. Sponsor is responsible for ensuring that changes requested by CRC are incorporated into the Submitted Material and to inform that Coordinator that the changes have been incorporated.

4.1.3. Sponsor shall be responsible for reviewing the Submitted Material prior to its submission into PromoMats to assure that it is free of typographical and spelling errors, that all the claims are properly tagged and linked to the supporting References, the References are correctly cited per

AMA style and attached (if needed), and that the Submitted Material is otherwise ready for publication.

4.1.4. Sponsor, or designee, is expected to attend CRC meetings to address questions and comments from the Reviewers.

4.1.5. Sponsor is responsible for incorporating any agreed-upon comments/edits received from the Reviewers on the Submitted Material or, as applicable, communicating these comments or edits to be made to a Third-Party Agency.

4.1.6. Sponsor is responsible for sending revised Submitted Material to the Coordinator to submit to the reviewers for re-review and final approval, after assuring that all changes required by the CRC are incorporated accurately.

4.1.7. Sponsor is responsible for ensuring that pieces intended to be used after Retirement Date are re-approved by CRC.

4.2. Coordinator

4.2.1. Coordinator is responsible for scheduling CRC meetings and ensuring that all Submitted Materials are tracked and distributed for review. Coordinator shall maintain an availability calendar of all members and reviewers.

4.2.2. Coordinator is responsible for submitting the final version of the piece to CRC for : (i) submission to the Reviewers for re-review and approval/rejection; and, (ii) dissemination/publication.

4.2.3. Coordinator shall carry out all administrative tasks that the CRC requires, including: (i) assuring that all Submitted Materials, linking and tagging to support References and Background Information have been properly uploaded into PromoMats prior to sending the Submitted Material to Reviewers; (ii) scheduling CRC meetings; (iii) preparing and distributing an agenda at least two business days in advance of each standing meeting; (iv) leading each meeting and maintaining the schedule as established on the agenda; (v) maintaining all CRC documentation and records in the validated PromoMats database; (vi) facilitating communication between Reviewers and Sponsors; (vii) facilitating communication between Sponsors and Third-Party Agencies; (viii) forwarding appropriate Final Submitted Material to the Regulatory Affairs Department; and, (ix) notifying the Sponsor when the Final Submitted Material is approved for dissemination.

4.2.4. Coordinator is responsible for maintaining documentation of all expedited reviews and reported to the Sponsor’s direct supervisor. Continual deviations will be be raised to the department head.

4.2.5. In the event that there is disagreement among CRC members requiring the review of Submitted Materials by the Escalation Committee, Coordinator shall facilitate meetings of the Escalation Committee, as needed.

4.2.6. Coordinator is responsible for notifying by email Sponsor and his/her supervisor two weeks prior to the next quarter of a Final Submitted Material's retirement. In the event that the Final

Submitted Material is not re-approved, Coordinator is responsible for notifying by email Sponsor and his/her supervisor that the piece must be retired.

4.3. **Regulatory Reviewer**

4.3.1. Regulatory Reviewer is responsible for review of Submitted Material from an FDA regulatory perspective (e.g., FDA regulations, Guidances (i.e. consistent with label), OPDP-issued Untitled and/or Warning Letters and correspondence, as well as industry standards).

4.3.2. Regulatory Reviewer is responsible for corresponding with OPDP when necessary, including addressing any comments received from them. Regulatory, should then communicate this correspondence to CRC.

4.3.3. If required, Regulatory Operations is responsible for submitting applicable materials and FDA Form 2253 to OPDP.

4.4. **Legal Reviewer**

4.4.1. Legal Reviewer is responsible for ensuring that Submitted Material complies with all laws, rules, regulations and SKLSI Standard Operating Procedures and policies pertaining to the advertising and promotion of SKLSI and SKLSI's pipeline products, including the Federal Food, Drug, and Cosmetic Act, Federal Trade Commission Act, Lanham Act, Copyright Act, federal and state anti- kickback, fraud and abuse, and transparency statutes (e.g., the False Claims Act and "Sunshine Act"), U.S. Department of Health and Human Services' Office ofthe Inspector general pronouncements (e.g., the Compliance Program Guidance for Pharmaceutical Manufacturers (2003)), PhRMA Code on Code on Interactions with Healthcare Professionals, and product liability Issues.

4.4.2. Legal Reviewer is responsible for ensuring that Submitted Material is consistent with obligations contained in third party licenses, co-promotion arrangements and other SKLSI commitments.

4.5. **Medical Affairs Reviewer**

4.5.1. Medical Affairs Reviewer is responsible for ensuring that all company and competitor data presented in any material is accurate, representative of the most current literature, consistent with product labelling or other data sources (e.g., data on file, clinical study reports) and relevant clinical practice.

4.5.2. Medical Affairs Reviewer is responsible for ensuring the validity and objectivity of the data contained in the materials reviewed by CRC, including data presented on efficacy, safety, patient populations, product use, and disease state information.

4.5.3. Medical Affairs Reviewer is responsible for ensuring that promotional claims are supported by data that meet FDA's statutory standards for "substantial evidence."

4.5.4. Medical Affairs Reviewer may assist, when needed, to help provide relevant published and data on file references.

5. PROCEDURE

5.1. General Overview of CRC

5.1.1. The CRC shall be responsible for evaluating all Submitted Material.

5.1.2. The CRC shall consist of the Reviewers, Coordinator and the Sponsor of the particular Submitted Material during its review.

5.1.3. Each Reviewer shall appoint a suitably trained and experienced alternate from his/her department (the "Alternate"). If a Reviewer cannot review the Submitted Material and/or attend a CRC meeting, the Reviewer's Alternate shall review the Submitted Material and/or participate in the CRC meeting. An Alternate's participation and decisions shall have the same force and effect as a Reviewer's participation and decisions. Similarly, if the Sponsor cannot attend a CRC meeting, an Alternate shall be designated to participate and agree to changes to the Submitted Material.

5.1.4. The Coordinator's supervisor shall appoint a suitably trained and experienced alternate ("Alternate Coordinator"). If the Coordinator unavailable, the Alternate Coordinator will serve in his/her place.

5.2. Submitted Material Review and Approval Process

5.2.1. The Sponsor (or a Third-Party Agency on behalf of the Sponsor) shall enter the Submitted Material, Background Information, and tag and link References and into PromoMats for the purpose of initiating the CRC process. The Coordinator must distribute Submitted Materials to the Reviewers within one business day of receipt. For example, Materials submitted prior to noon will be distributed by noon the following business day.

a. It is the responsibility of the Sponsor to ensure that Submitted Material is submitted for approval prior to production, publication, dissemination, or distribution. Except as described below, no Submitted Material shall be produced, published, disseminated, or distributed before Sponsor's receipt of the approval of the CRC transmitted through PromoMats (which will include notification that the Regulatory Affairs Department has made any required submission of the Submitted Material to OPDP).

b. In exceptional circumstances and when time is of the essence, Sponsor may seek the approval of the CRC (which will include notification that the Regulatory Affairs Department has made any required submission of the Submitted Material to OPDP) via email. The Sponsor shall copy the Coordinator on all such emails, and all Submitted Materials approved in this manner must be subsequently approved through PromoMats for recordkeeping purposes. When such material is subsequently uploaded into PromoMats for approval, Sponsor (or a Third-Party Agency on behalf of the Sponsor) must

clearly note to the reviewers that the material has been previously approved via e-mail and attach the e-mail approvals from the reviewers.

5.2.2. The Sponsor (or a Third-Party Agency on behalf of the Sponsor) shall upload into PromoMats the Submitted Material, tag and link References and Background Information according to schedule below:

Initial Review	
Number of Pages	Number of Review Days[1]
≤ 30	4 business days
> 30	7 business days
*Review time may deviate based on quality of submission, as well as depth of review (e.g., references, linking/tagging, etc.). Coordinator will discuss potential deviations with the Sponsor. me is necessary.	
Approved with Changes Review	
≤ 30	1 business day
> 30	2 business days

5.2.3. Under limited circumstances, the Reviewers may consent to shorten the applicable review period as determined by the needs of the business. Accelerated review period rationale should be documented and approved by the Sponsor's supervisor.

5.2.4. Sponsors shall not ask Reviewers to provide comments at a CRC meeting on materials (Submitted Materials or otherwise) that have not been previously reviewed without providing the material to the Reviewers in advance. In the event that a concept review is requested, the Sponsor should provide materials to the reviewers at least 24 hours in advance of the meeting.

5.3. **Pre-Processing of Requests**

5.3.1. The Coordinator shall review each uploaded Submitted Material, References are tagged and linked, and Background Information to ensure that they are complete. In the event that they are not complete, the Coordinator shall mark the file as "incomplete" and return it to the Sponsor for completion.

5.3.2. If the Submitted Material, tagging and linking of References and Background Information are complete, the Coordinator shall release the Submitted Material within PromoMats so that it is sent to the Reviewers.

5.4. **Review and Approval Process**

[1] The day of CRC meeting is not counted as a review day.

5.4.1. Upon notification by PromoMats that a Submitted Material is pending, each Reviewer shall promptly review the Submitted Material, tagged and linked References and Background Information.

a. Reviewers are to provide comments to Submitted Material within their respective areas of expertise. Reviewers should focus their efforts on ensuring that Submitted Material is truthful, non-misleading, properly substantiated and balanced, consistent with the approved Package Insert and compliant with federal law (including, FDA regulations and guidances).

5.4.2. The Coordinator shall establish a schedule of standing weekly meetings (i.e., on a set day and time period) at which they and Sponsor(s) will collectively review Submitted Material(s), and/or have concept discussions (the materials for concept discussions should be provided to reviewers 3 days prior to meeting), clarify comments, resolve differences, and reach consensus on the final version(s) of the Submitted Material(s).

a. The Coordinator shall prepare and distribute an agenda for each CRC meeting at least two business days prior to each meeting. In the event that comments on the Submitted Materials can be addressed without a meeting, the Coordinator may cancel the standing meeting.

b. All Submitted Material reviewed by the CRC shall be designated as (i) "Approved for Production;" (ii)"Approved with Changes;" or, (iii) "Not Approved." This determination shall be documented in PromoMats.

- Approved for Production: In circumstances where there are no changes made to Submitted Material and the CRC unanimously agrees, all Reviewers shall select "Approved for Production" in PromoMats.
- Approved with Changes: In circumstances where the Reviewers make changes to the Submitted Material, they may authorize the Sponsor to make those modifications at which point the Submitted Material are deemed Approved without further review by the Medical and Legal Reviewers. All final pieces are to be seen in final state by the Regulatory Reviewer.
- NOTE: One or more Reviewers may request that the Submitted Material be re-submitted for review by only that Reviewer or the entire CRC after the changes are implemented. The Reviewer(s) reviewing the Submitted Material after the changes are made must then Approve the piece before it may be released.
- Not Approved: The Coordinator shall reroute Submitted Material designated as "Not Approved" to the Sponsor (or designee) of the piece so that the Submitted Material may be modified and resubmitted to the CRC for approval, as appropriate. The Sponsor shall incorporate all agreed upon changes prior to resubmitting the Submitted Material for CRC re-review and approval.

c. The Coordinator shall memorialize all changes to the Submitted Material made during the CRC meeting and shall retain the original and all Annotated Submitted Materials.

5.4.3. If the results of the Reviewers' reviews are such that the Coordinator determines that a meeting is not necessary, the Coordinator may cancel the meeting.

5.4.4. In the event that the Reviewers and Sponsor cannot unanimously agree on the final content of the Submitted Material, the "Conflict Resolution and Escalation Process" shall be used.

5.5. **Post-Review of Submitted Material**

5.5.1. Upon production of the Final Submitted Material, the Sponsor shall ensure that the Final Submitted Material is identical to the Annotated Submitted Material approved by the CRC. Any changes - no matter how minor - subsequent to the Reviewers' approval of Submitted Material (i.e., Final Submitted Material) shall require a re-review and approval of the Final Submitted Material by CRC.

a. Changes should be submitted at least 48 hours prior to the use of the Final Submitted Material.
b. For event-related Submitted Materials (e.g., Advisory Boards, Speaker Programs, etc.), at least one week prior to the event, on-site walk through date and time should be provided to the CRC members. In the event that onsite changes are necessary, members should be available for additional review and approval.

5.5.2. For materials requiring 2253 submissions, upon receipt of the Final Submitted Material, the Coordinator shall forward the Final Submitted Material to the Regulatory Affairs Department no later than five business days prior to the anticipated date of publication or dissemination.

a. If publication or dissemination of the Final Submitted Material is not to begin immediately (e.g., if SKLSI is seeking advisory comments from FDA), the Coordinator shall also inform the Regulatory Affairs Department or authorized designee of the anticipated date on which the material is first to be published or disseminated.
b. It is the responsibility of the Regulatory Affairs Department or authorized designee to submit Final Submitted Material to OPDP at the time of initial publication or dissemination, as required by FDA regulations. If SKLSI is seeking advisory comments from FDA, Final Submitted Material must be submitted to FDA well in advance of the anticipated date on which the material is first to be published or disseminated (i.e., generally, 60 days prior to the anticipated date of publication or dissemination and 30 days for DTC television advertisements).

5.6. **Conflict Resolution and Escalation Process**

5.6.1. In the event that the CRC members cannot reach unanimous agreement about the disposition of a Submitted Material during a PMRC or MRC meeting, the Coordinator will schedule a meeting with the Escalation Committee, along with the Sponsor.

5.6.2. A Submitted Material must have unanimous approval from the Escalation Committee prior to use by the Sponsor.

5.6.3. If the Escalation Committee is unable to resolve the disposition of the Submitted Matter unanimously, the Submitted Material will be escalated to the Chief Executive Officer (CEO).

5.6.4. The CEO will be informed of all Escalation Committee decisions.

5.7. **Modifications to, and Retirement of Final Submitted Materials**

5.7.1. If a Sponsor wants to use Final Submitted Material in any of the following situations, it must be re-submitted for review and approval by CRC:

a. Final Submitted Material to continue to be used after its Retirement Date.
b. Final Submitted Material for which the audience has changed (e.g., Final Submitted Material originally approved for healthcare professionals being redesigned for patients

or Final Submitted Material approved for use in one publication being used in another publication).

c. Final Submitted Material for which the medium has changed (e.g., Final Submitted Material originally approved as a printed brochure, being republished as a website).

5.7.2. In the absence of a re-review and approval, prior to a Final Submitted Material reaching its Retirement Date, Sponsor shall be responsible for establishing a timeline for: (i) destruction of any Final Submitted Material inventory; and, (ii) notifying SKLSI Personnel (including any contractors) that the Final Submitted Material is not to be utilized after the Retirement Date and is to be destroyed or returned to headquarters.

6. DOCUMENTATION REQUIREMENTS

None

7. REFERENCES

None

8. LIST OF ATTACHMENTS

8.1. Appendix A: Examples of Submitted Material Requiring Review

Document Approvals

Approved Date: 13 Mar 2020

Task: SME Approval Verdict: Approve changes & release	Monica Schroeter, (mschroeter@sklsi.com) SME Approver 03-Mar-2020 19:33:04 GMT+0000

Task: SME Approval Verdict: Approve changes & release	Sebastian Borriello, (sborriello@sklsi.com) SME Approver 03-Mar-2020 19:35:40 GMT+0000

Task: SME Approval Verdict: Approve changes & release	Darshan Patel, (dpatel@sklsi.com) SME Approver 10-Mar-2020 18:28:44 GMT+0000

Task: SME Approval Verdict: Approve changes & release	Louis Ferrari, (lferrari@sklsi.com) SME Approver 12-Mar-2020 19:43:39 GMT+0000

Task: QAQC Approval Verdict: Approve changes & release	Hong Wook Kim, VP, Chief Operating Officer (hwkim@sklsi.com) QA Approval 13-Mar-2020 12:20:30 GMT+0000