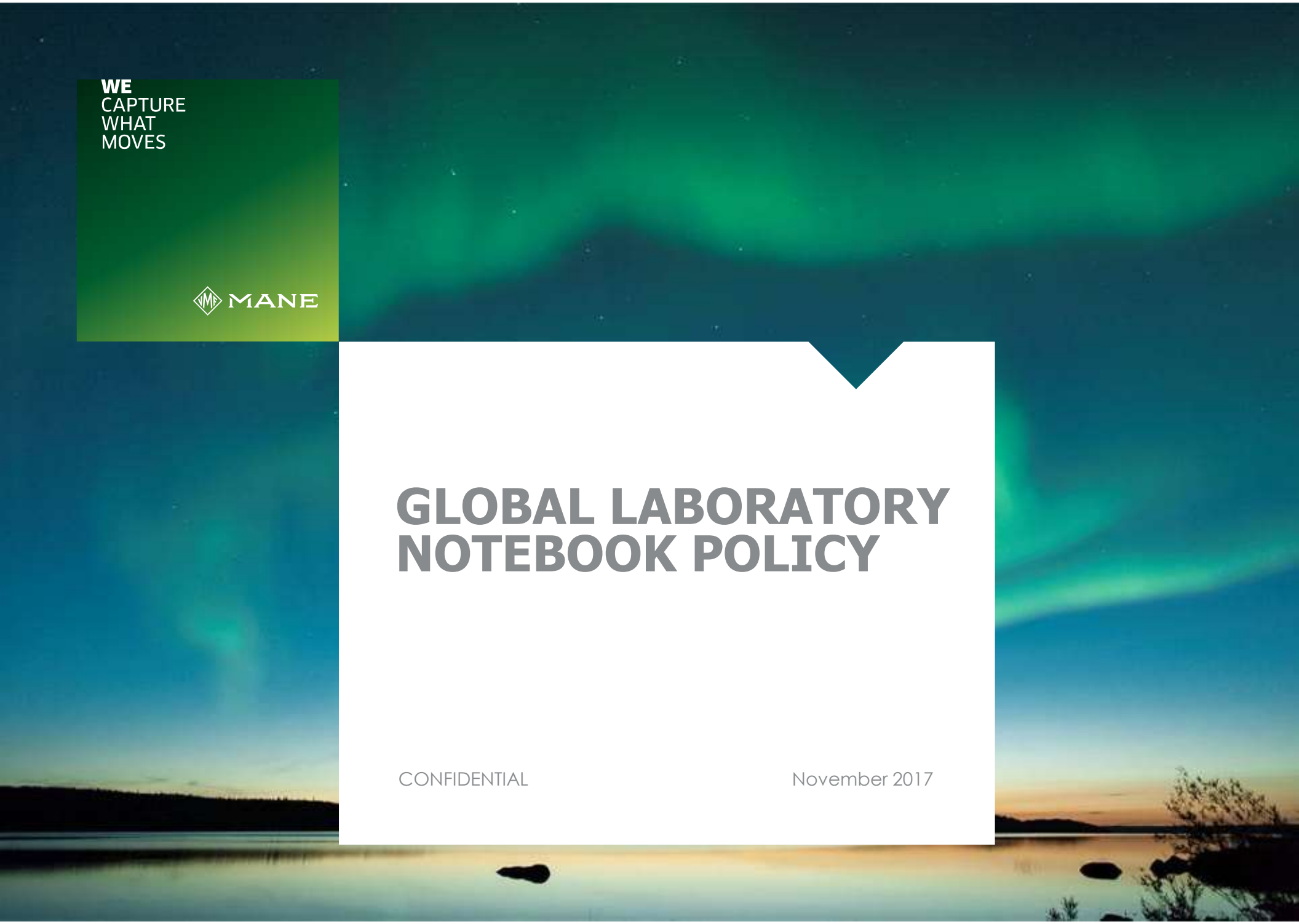

GLOBAL LABORATORY NOTEBOOK POLICY

CONFIDENTIAL

November 2017

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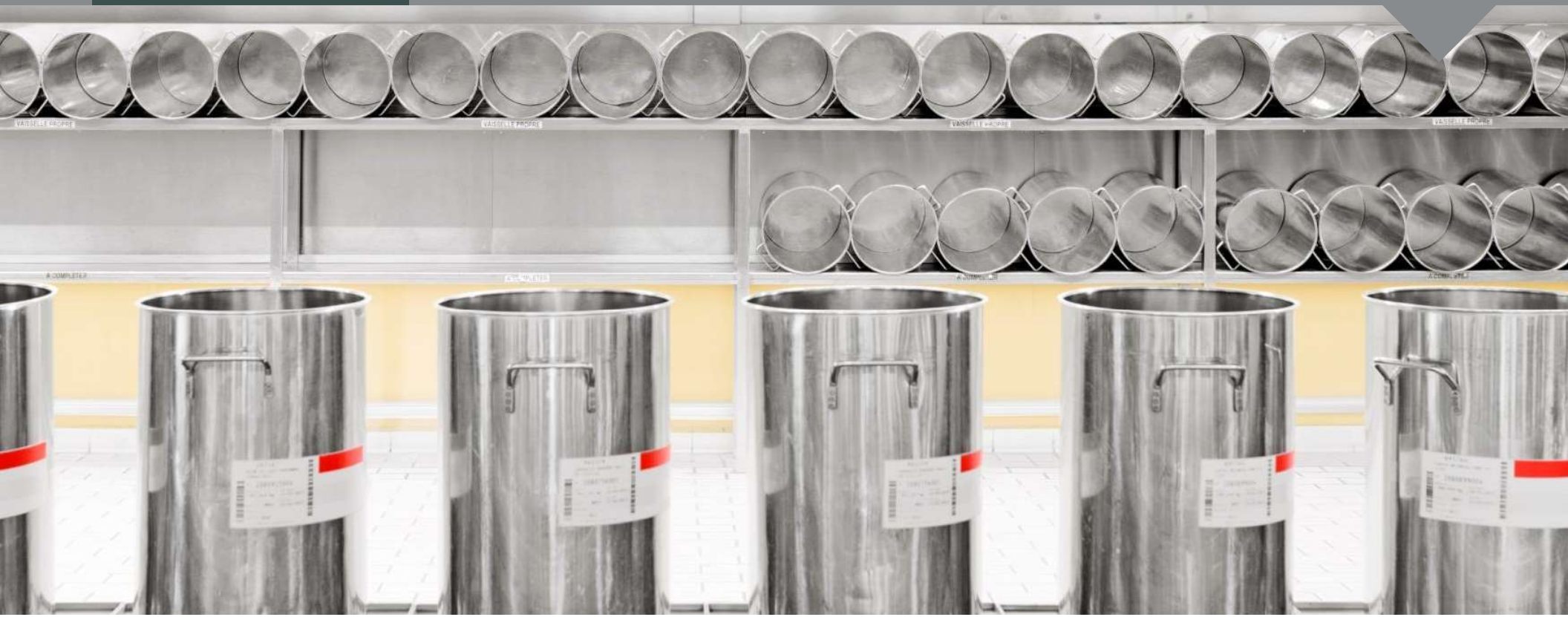
01 IMPORTANCE OF LABORATORY NOTEBOOKS



IMPORTANCE OF LABORATORY NOTEBOOKS

The primary purpose of a laboratory notebook is to preserve and protect intellectual property rights in all new and improved products, processes, or equipment by serving as ***a record and archive*** for all research and development work (ideas, experiments, formulations, etc.).

A properly executed laboratory notebook may be used as legal evidence with respect to various aspects of the new or improved methods/products, such as conception and/or reduction to practice of an invention and date(s) corresponding thereto, test results, and the like.

- **A chronological record and the primary document of a person's work in a research laboratory.**
- **A complete record of procedures, reagents, data, and scientific interpretations and hypotheses to pass on to other researchers.**
- **A document that records factual details of experiments, including thought experiments, ideas, inventions, etc.**

IMPORTANCE OF LABORATORY NOTEBOOKS

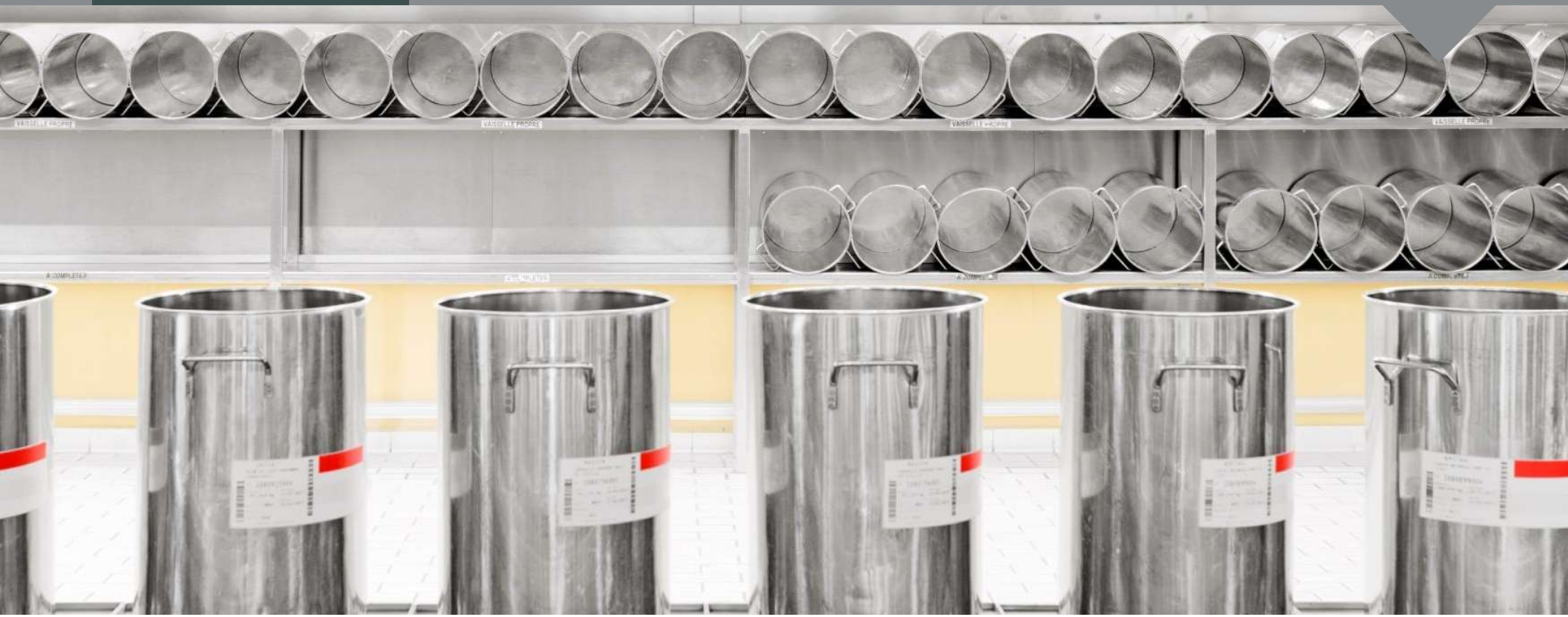
It is Critical and Required!

- Recording what you did, so you *or others* can repeat the experiments.
- Good records make it easier to publish or share results.
- Troubleshooting: help find mistakes, bad materials, etc.
- Legal document for evidence in patent and trade secret matters.
- Defense against accusations of fraud or lawsuits

Your data should be able to be explained, defended, reconstructed, or repeated without your assistance.

02

US CASE LAW CITING USE OF LAB NOTEBOOKS



US CASE LAW

Since 2012, over 30 federal cases have been decided where laboratory notebooks were amongst the evidence considered by the court and referenced in the court's opinion.

Used as evidence to show:

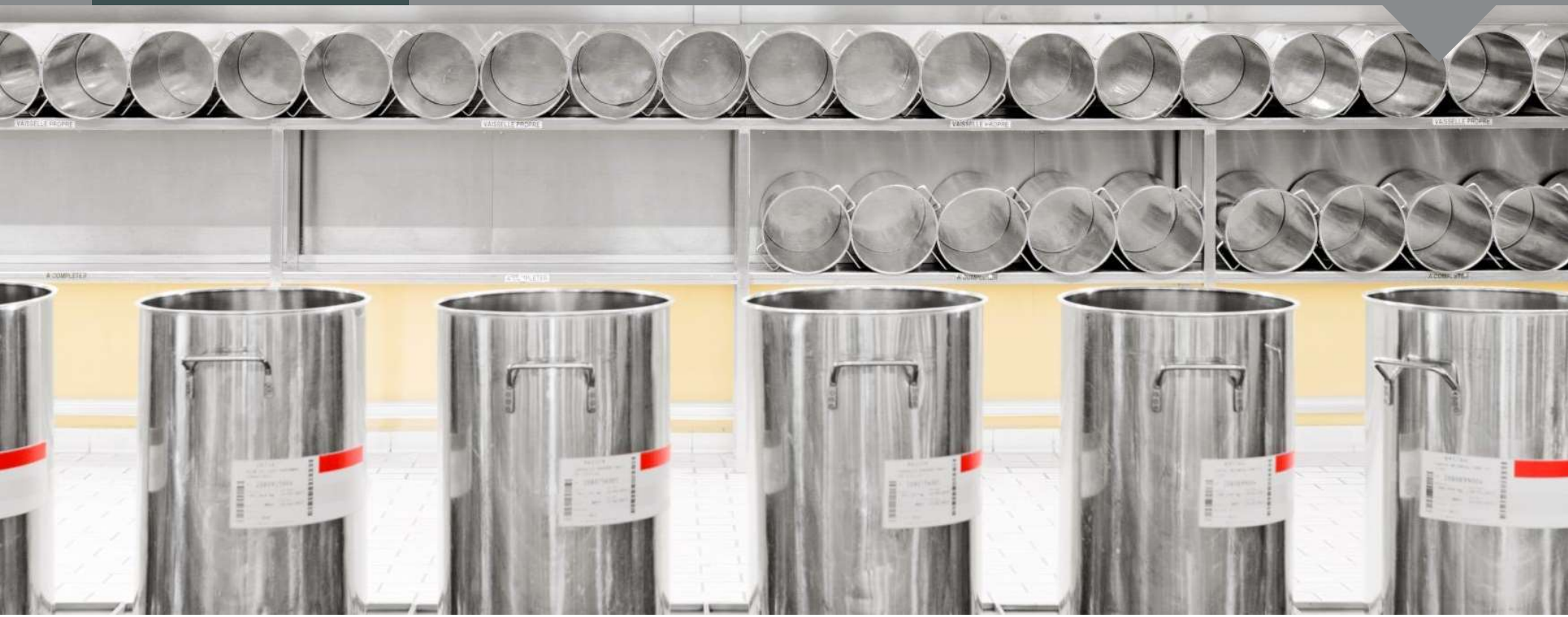
- Conception date of an invention
- Reduction to practice date of an embodiment of an invention
- Date of first observation or discovery of a new polymorph
- Date that a research idea was shared with a colleague (who later tried to patent himself)

Notable excerpts:

- "an unwitnessed entry in an inventor's laboratory notebook was insufficient, without more, to corroborate the inventor's testimony that he had conceived of the invention."
- "… whiteboard photos are analogous to the unwitnessed pages of a laboratory notebook and would therefore likely be insufficient on their own to corroborate inventor's testimony of prior conception."
- "…had not signed his laboratory notebook for nine months, then curiously signed his notebook…"

03

NOTEBOOK AND METHODS



NOTEBOOK AND METHODS

What to record for an experiment?

- **Start Date**
- **Title**
- **Why:** Rationale, hypothesis, objectives
- **Methods (Plan):**
  - Standard Operating Procedures (SOPs) with references
  - Planned protocol modification, why, and approval
  - Calculations: MW, concentrations, dilutions, formula, …
- **What Happened (Realities):**
  - Sample preparation
  - Experiment /test conditions;
  - Results, including unexpected results or observations
  - Document critical events to prove compliance with SOPs
- **What It Means:**
  - Result interpretation, including comments on oddities
  - Potential uses
- **What's Next:** Future plans
- **Ideas, hints and tips:** Use notebook as a repository of creativity

NOTEBOOK AND METHODS

2.1. General Rules Regarding Form

- Preferably, the language of the laboratory notebook is English, but French or Spanish may be acceptable alternatives depending on the location of the Mane Innovation center.
- The information is recorded directly in the laboratory booklet, dated (using two digits for the day, at least three letters to uniquely identify the month, and four digits for the year, e.g., 20 MAY 2017 or 05 NOV 2017), and referenced with its company project name or number and/or an internal reference specific to the researcher.
- The recording of handwritten information is done directly and only on the printed lines of the pages of the notebook, respecting the full width of the pages.
- The insertion of information near the internal margin is to be avoided, as information may be difficult to capture accurately during scanning.

Note 3: *If the need for a later entry or amendment arises, it is advisable to use unmarked section of the page immediately below, and particularly point out the passage(s) concerned. Where no such unmarked section is available, one should make the entry/amendment on a subsequent page, and record the subsequent page number on the instant page. An arrow, asterisk, etc. can be used to precisely identify the section being amended or corrected.*

NOTEBOOK AND METHODS

- Recording data can also be carried out by means of inserting preprinted information in the notebook (for example, typed reports, diagrams, diagrams, output datum of equipment of analysis, photographs, etc.). The preprinted information should not exceed the dimensions of the page, nor cover any information already entered on the page. Transparent tape or other adhesive should be utilized to affix the inserted information to the page surface.
- For two successive inserts, the second must be affixed below the other (or on two successive pages) and not side by side. Each taped or glued insert must be signed and dated by both the writer and the witness (each signature should traverse at least one of the seams between the insert and the support page). Other than the aforementioned dates and signatures, no other handwritten annotations on the insert are permitted.

Note 4: *If there is a need to annotate information on an insert (e.g., for reasons of clarity), the "original" preprinted copy must be annotated first and then photocopied; the corresponding photocopy is then adhered to the surface of the notebook page.*

Note 5: *It is not necessary to integrate every piece of data in the laboratory notebook. For example, if the data set is too large, the writer can also create alternative archives for the data (e.g., an electronic database of HPLC chromatographs), and simply reference the corresponding file number.*

Note 6: *Rather than the original of an experimental material, a photograph or a digitized reproduction may be used, such as in the case of a thin-layer chromatography plate, a gel, a membrane, an autoradiography, or a thermosensitive ticket.*

NOTEBOOK AND METHODS

Supplemental Materials

- Examples of information that could be inserted (taped) into a notebook:
  - Computer-generated data
  - Datasheet templates
  - E-mails
  - Notes of discussions and conversations
  - Photographs
  - Printed graphs
  - Product labels
  - Related papers and readings
- **If too large to fit, items may be kept in a separate folder** Always record date and other identifying information
- Provide "links" to equipment logbooks, data on computers, other notebooks, journal references, etc

NOTEBOOK AND METHODS

- Significant blank spaces between two information entries (for example, successions of blank lines, page breaks, pages left blank) or to the right of an insert, must be crossed out by means of a "Z", so that no information may be subsequently added. The removal of any laboratory notebook page is strictly prohibited, as doing so may jeopardize the integrity of the entire notebook.

- All handwritten entries shall be made using permanent ink. There is no restriction on the choice of ink colors to be used, provided that the recorded information remains fully legible and comprehensible in full, after black and white reproduction using a standard photocopier.

- Black or dark blue inks are recommended. The use of erasable ink, pencil, or "white correction fluid" is not allowed. The texts and entries must be legible (any erasure must be referred to and dated, both by the editor and the witness).

- Any coding of information using specific colors should be avoided. If the use of colors cannot be avoided, the selection of colors and/or textures must be made with careful consideration of a possible need for subsequent reproduction using a standard photocopier in black and white.

- On each page containing an entry, the name of the project and laboratory notebook number must be entered in the designated location at the top of the page.

NOTEBOOK AND METHODS

2.2. General Rules Regarding Substance

Each test, experiment, or analysis, whether positive or negative, must be recorded in the laboratory record. Care should be taken to ensure that the following elements are clearly and precisely stated:

- The context in which the work was carried out, the objectives set and/or the problem to be solved, the working hypotheses, etc.;
- The experimental conditions used (protocols, particular parameters and material used ...); and
- The results obtained, their possible interpretation, as well as any ideas, reflections or comments relating thereto.

Abbreviations may be used. However, abbreviations that are non-standard to persons having ordinary skill in the relevant field must be defined at their first appearance. Further, abbreviations, along with their definition, should also be recorded after the table of contents/index section at the front of the laboratory notebook.

NOTEBOOK AND METHODS

Note 7: *If a protocol has already been previously described, in the same or different laboratory notebook, it is not necessary to reproduce the entire information for a new entry. Rather, it is sufficient to simply reference the previous occurrence with particularity, i.e., the laboratory notebook number and page(s) concerned along with the name of its author. All modifications, changes, or adaptations to the referenced information must be sufficiently described. Referencing scientific publications or books is permissible if identified unambiguously using a full bibliographical citation.*

Note 8: *It is possible to create a separate laboratory notebook specifically reserved for recording standard laboratory or testing procedures and protocols, abbreviations, etc., and then make an appropriate reference to this separate laboratory notebook.*

NOTEBOOK AND METHODS

Duties of the author:

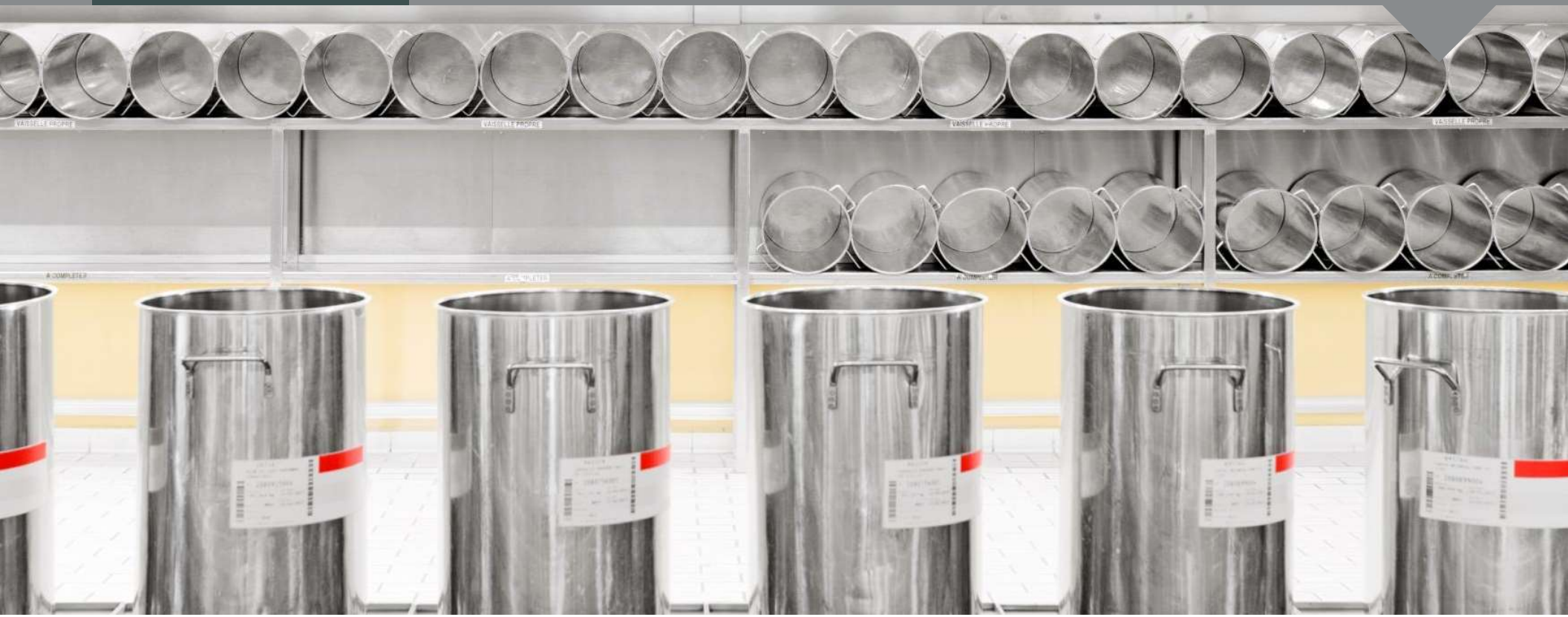
- Each page must be dated.
- Each page of the laboratory book, as soon as it is completed, must be dated and signed by the author, in the space designated for this purpose.
- Any mistakes or crossed-out entries, as soon as they appear in the laboratory book, must be dated and signed by the author.
- Do not insert any information (including corrections) in a corner of a page (even if that page has not yet been countersigned by a witness).
- If any error or mistake is identified, the erroneous information should be clearly identified and corrected in a space immediately below the error. If there is no available space or the available space is insufficient, then corrections may be made on a subsequent page (with an appropriate forward reference on the page bearing the erroneous information). If the date on which the error was found and/or corrected is different from the origin date, said correction date should be properly recorded.
- Unused lines or space at the bottom of the page should be crossed out using a "Z" marking.
- In order to certify the reality of the recording, the author must have a witness sign each of the pages of his laboratory notebook within a maximum of 4 weeks after the writing of each of these pages.
- No new information or data integration can be entered onto any page that has been already signed by a witness.

NOTEBOOK AND METHODS

Duties of the witness:

- Read the information entered by the author/researcher to evaluate whether the level of detail is sufficient to enable its reproduction by another having ordinary skill in the relevant art.
- Co-sign all taped or glued inserts. The date and signature must be affixed astride the insert and its supporting page surface.
- Verify the quality of the information with regard to compliance with Mane's Laboratory Notebook Policy, along with laboratory recordkeeping procedures found at the front of the laboratory notebook itself.

04 REVIEW, CERTIFICATION, AND ARCHIVAL PROCESS



REVIEW, CERTIFICATION, AND ARCHIVAL PROCESS

3. Certification

The holder/assignee of a laboratory notebook must have it certified, twice a year at the time of certification sessions organized in May and November, by a member of Mane's Legal and IP Department.

- All laboratory notebooks, in progress or completed, must be submitted to the Legal and IP Department on the working day immediately preceding the certification date.
- Prior to this submission, the holder of a laboratory notebook must ensure that the information in each laboratory notebook is correctly recorded, including marking out any significant empty space (e.g., marked out with a "Z"), updating the table of contents, as well as arranging for the proper witnessing of the notebook.

During certification, each laboratory notebook shall be inspected with regard to compliance with this policy. At the end of this inspection, the reviewer will make an entry into the notebook and notate the completed inspection by affixing the reviewer's stamp, date, and signature.

At the end of each certification, the notebook will be promptly returned to its assignee, ideally no later than the next working day after certification.

For remote Innovation sites, arrangements will be made based on the volume of laboratory notebooks to enable completion of the certification process without undue expense of time or resources.

REVIEW, CERTIFICATION, AND ARCHIVAL PROCESS

4. Archiving

Each person assigned to a laboratory notebook is responsible for the maintenance of the notebook while it is in his/her possession.

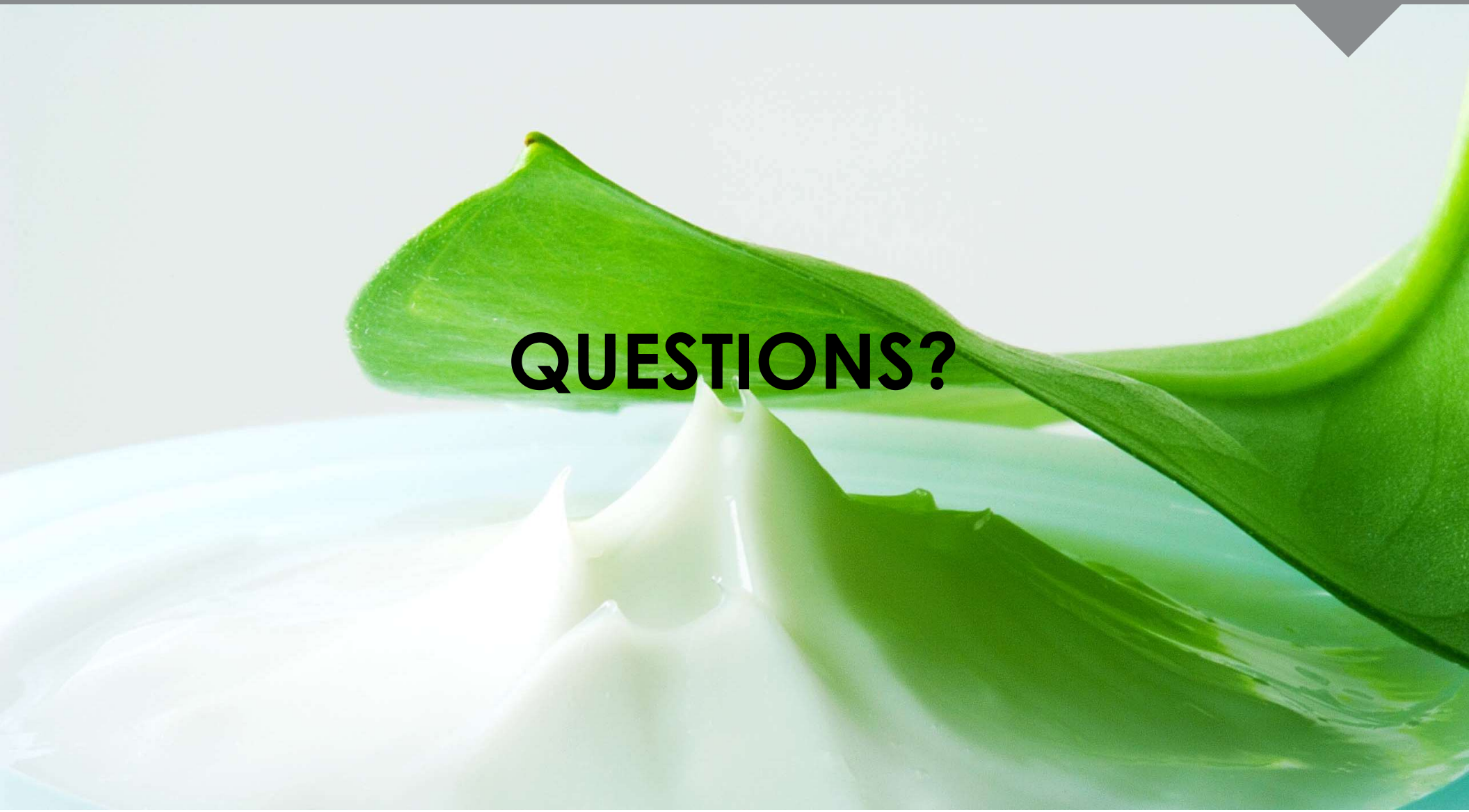
- must ensure that each assigned laboratory book (s) is stored in a safe and secure location to prevent loss, theft, or degradation.
- If a laboratory notebook is lost, stolen, or damaged, the assigned person shall immediately notify his/her supervisor.
- Prior to preserving an electronic copy of a laboratory notebook, the holder must ensure that
  1) the content of the notebook meets the standards set forth in this policy, and
  2) The notebook is certified (per Section 3 above).

Once a notebook is complete and certified, the holder should make arrangements with the VP of R&D to begin the laboratory notebook scanning/archiving process.

After securing an electronic archival copy of the laboratory notebook, the original hardcopy will be returned to its originally assigned holder for a reasonable period, which shall not exceed three (3) years from the date of last entry.

After the reasonable retention period, VP of R&D (or site Director) will arrange for long term storage of the notebook within a fire resistant container at the local Mane Innovation site.

CONCLUDING REMARKS



WE
CAPTURE
WHAT
MOVES

MANE

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