

REQUEST FOR INFORMATION

**Automated visible particles Analytical instrument**

July 19, 2021

Enabling Technologies Consortium™

Request for Information

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# Introduction

## About Enabling Technologies Consortium™ (ETC)

The Enabling Technologies Consortium™ (ETC) is comprised of pharmaceutical and biotechnology companies collaborating on issues related to pharmaceutical chemistry, manufacturing, and control with the goal of identifying, evaluating, developing, and improving scientific tools and techniques that support the efficient development and manufacturing of pharmaceuticals. The purpose of this consortium is to identify pro-actively high-value opportunities to deliver innovative technologies where the business case is compelling and collaboration with the broader external community is required.

## Request for Information

Publication of this Request for Information (RFI) is the first step by ETC to solicit interest in collaborating on the project titled “**Automated Visible Particle Analysis Instrument.”** The information collected during the RFI process along with subsequent interviews will be used for evaluation purposes. Depending on the responses received ETC may choose to select a collaborator solely based upon its response to the RFI or may choose to refine project requirements and subsequently release a Request for Proposals (RFP) to aid in the collaborator selection process.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in developing the project “**Automated Visible Particle Analysis Instrument.”** The successful respondent selected by ETC at either the RFI stage or RFP stage (if applicable) will be required to execute an Agreement that will govern the terms of the project. When responding to this RFI, please note the following:

* This RFI is not an offer or a contract
* Responses submitted in response to this RFI become the property of ETC
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFI process
* If ETC receives and responds to questions from RFI respondents, ETC reserves the right to anonymize the questions and make the questions and ETC’s responses available to all respondents via our website
* Responses to RFIs should contain only high-level discussions of product development efforts and should not contain trade secrets or confidential information. ETC does not make any confidentiality commitments with respect to RFI responses but agrees not to publicly distribute RFI responses outside of ETC or share RFI responses with other respondents.
* ETC is not obligated to contract for any of the products or services described in this RFI
* ETC reserves the right to:
	+ Accept or reject any or all proposals
	+ Waive any anomalies in proposals
	+ Negotiate with any or all bidders
	+ Modify or cancel this RFI at any time

## RFI Contact Information

All questions and inquiries regarding this RFI should be directed to:

Ms. Fatou Sarr

ETC Secretariat

c/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

202.230.5148

info@etconsortium.org

<http://www.etconsortium.org/>

## Anticipated Time Frames for Evaluation and Selection Process\*

Issue RFI July 19, 2021

Questions on RFI due (via email) August 2, 2021

ETC responds to any RFI questions August 13, 2021

Responses from potential collaborators due August 20, 2021

Invitations sent to respondents for presentation September 13-24, 2021

Presentation to ETC by respondents Sept 20 - Oct 8, 2021

Select finalists for RFP or select a collaborator October 11-29, 2021

*\*Dates subject to change without notice*

***Please submit your response electronically to the above address. Responses received after August 20, 2022 will not benefit from full consideration and may be excluded from the selection process.***

## Project Scoping and Project Execution

ETC project sponsors will work with the selected collaborator to define the project scope and work to finalize a Statement of Work (SOW) for the project which describes project timelines, milestones, budget, deliverables, etc. Depending on the project, the scoping exercise will be conducted via email, web-meetings, and/or an in-person workshop. Following finalization of the SOW, the project will be brought forward to the ETC Board of Directors to authorize moving to execution.

Once authorized by the ETC Board of Directors, the ETC Secretariat will work with the selected collaborator to negotiate and finalize a contract between the two parties, leveraging ETC’s Development Agreement and Non-Disclosure Agreement accelerator templates. In parallel to this negotiation, the Secretariat will also work to finalize and execute our internal project Charter between participating ETC members.

## Intellectual Property

ETC acknowledges that this project, or aspects thereof, may require the use and incorporation of existing intellectual property and/or the development of new intellectual property in order to successfully complete the project.

### Existing Intellectual Property

* ETC as an organization will not engage in negotiations with the owner of any intellectual property on the respondent’s or ETC’s behalf;
* It is the responsibility of the respondent to conduct an intellectual property search and take all necessary steps to ensure their proposed project will not infringe or misappropriate any intellectual property right of a third party and/or obtain all necessary consents, assignments and licenses to provide the solution in the project proposal.
* Any existing intellectual property that ETC is aware of that may be relevant to this project is provided as **Appendix A**.

### New Intellectual Property

With most projects conducted with ETC:

* All commercialization rights will reside with the collaborator;
* ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

# Project Information

## Possible Project Sponsors

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| Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Genentech, GlaxoSmithKline, Johnson and Johnson, Merck, and Takeda. |

## Description

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| Visual inspection is routinely used in parenteral products to ensure that the product does not contain visible particles. Visual inspection is most commonly performed by trained operators using their naked eye. Human based visual inspection is probabilistic in nature; the lower particle size detection limit and the outcome of visual inspection depends on various factors, such as the examination settings, the operator’s experience and visual acuity, primary packaging, formulation properties, and particle properties. Depending on the listed factors, usually particles larger than 50-400 µm (depending on particle type and product properties as well as inspection parameters) can be detected through visual inspection. Because of the dependency on the operator's ability and judgment, semi-automated and fully automated visual inspection methods have been developed to improve and standardize the inspection process. Semi-automated systems relieve the human operator from holding and swirling the container, thereby standardizing the sample preparation process. Furthermore, auxiliary devices such as light from the bottom or a magnifying lens in front of the analyzed container improve particle detection. However, the detection process and the evaluation itself still need to be performed by the examiner and rely on the operator's ability to detect particles and their judgment. In contrast, fully automated systems detect particles by light reflection and transmission with subsequent image analysis to distinguish particles from container defects. As a limitation, automated visual inspection only distinguishes between absence and presence of visible particles and does not provide information about particle properties such as number, size, morphology, or origin [Zölls et al, 2012]. There are inconsistencies in which size ranges are to be included in the automated inspection process (e.g., lower size limit to be assessed) and the rate of falsely rejected units (particle-free units classified as particle containing by error) needs to be reduced. The ETC is seeking information from companies interested in supplying a commercially viable, automated instrument for the analysis of “visible particles” that are 30 µm and above in size. This instrument must allow non-invasive, non-destructive (no impact on the sample quality and property) measurement of particles and robust data analysis of particle shape, number, and size. The sections below detail the system requirements as identified by a working group within ETC. The consortium is seeking information from vendors regarding technologies that might be amenable to collaborative development. |

## Automated Visible Particle Analytical Instrument Requirements

### Necessary Hardware and Software Requirements

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| Hardware Requirements:* The instrument and accessories should be capable of handling various type of containers, including but not limited to pre-filled syringes (PFS), vials, cartridges, rigid glass, and transparent plastic containers with volumes up to 50 mL.
* The instrument should be able to analyze clear to opalescent (≈30NTU) solutions, including small molecule product solutions, biologics, new modalities with viscosities up to 50 cP.
* The instrument should be scalable to adapt to different sample sizes; the more flexible, the better.
* The instrument should be useable in a typical laboratory environment.
* The instrument should be able to provide information on the particle properties (i.e., morphology, solution behavior, optical properties), be able to differentiate accurately and consistently air bubbles from particles, and possibly classify particle types, e.g. protein particles/inherent particles, silicone oil droplets, and extrinsic particles (cells, fibers).
* The instrument should be able to capture and display information on individual particles, such as images for optically based equipment.
* The instrument should be able to run a diagnostic and system suitability test (e.g., light intensity check, particle count standard, etc.)

Software Requirements – User Interface* A simple and intuitive interface for use by non-specialists is required.
* Setup to enable a sequence of analyses (e.g. sampling interval, method parameters, number of samples, etc.) should be available in a user-friendly fashion that requires minimal training or minimal special expertise.
* There is a requirement for simple output in a standard data/reporting format (e.g. Allotrope Foundation) to enable integration with process data management systems. Output via OPC-UA or other standard formats is desired for system integration.

Other System Requirements * Vendor provided IQ/OQ process.
* Both equipment and software should have a migration path to be fully compliant with GMP regulations (i.e. 21CFR part 11 and data integrity rules)
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### Optional Hardware and Software Requirements

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| * Capable of in-line/on-line integration
* Capability of applying AI and/or machine learning
* Ability to minimize product-specific method development/validation
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### Availability Requirements

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| * Commercially available and supported system.
* Any requisite service on the instrument should be available globally.
* Vendor-provided, hardware and software support is expected for the reasonable life of the product.
* Hardware, software, and firmware updates should be field deployable and available at reasonable cost following launch of the commercial technology.
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### Licensing Requirements for Commercialized Product

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| * Software will be licensed to ETC participants at no cost during (i) development and (ii) a mutually agreed beta testing period.
* Thereafter, software will be available for licensing on a perpetual basis or subscription basis at the option of customer.
* The collaborator shall make available industry standard support.
* Software shall be available for self-hosting by (or on behalf of) customer even if the collaborator elects to make a SaaS alternative available.
* Ownership of data generated on system resides with customer.
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# Criteria for Evaluation

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| The ETC will evaluate the responses to this RFI based on the respondent’s ability to:* Provide responses reflecting a desire to participate in collaboration.
* Meet the functional, performance, and technical requirements described in this RFI as evidenced by the RFI response and presentations made to ETC.
* Provide a cost-effective solution that is compatible with the goals of the project.
* Demonstrate domain expertise and an ability to work collaboratively with the ETC in development of an automated visible particle analytical instrument.
* Provide a superior level of customer service and technical support, both pre-installation and post-installation to clients.
* Discuss potential partnerships and current development efforts that show similarities to this RFI.
* Provide any additional capabilities that may differentiate them from other potential collaborators.

The ETC will not provide individual feedback directly to RFI respondents beyond the status of their response to this RFI. |

# Respondent Profile *(to be completed by RFI respondent)*

Please provide information to the following:

## Company/Organization Information

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| --- | --- |
| Company/Organization Name |  |
| Address |  |
| City |  |
| State |  |
| Country |  |
| Zip Code |  |
| Website |  |

## Primary Contact Person

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Email address |  |
| Phone Number |  |

## Company/Organization Overview

Provide a brief overview of your company/organization including number of years in business, number of employees, nature of business, description of clients, and related products developed and commercialized to date.

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## Parent Corporation and/or Subsidiaries

Identify any parent corporation and or subsidiaries, if appropriate.

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## Summary of Expertise

Give a brief description of your company/organization’s expertise in the area/field related to this RFI. Include any experience working on projects with Consortia/Associations.

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## Standards Certifications

List any certifications currently held, including date received, duration, and renewal date.

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## Goals and Strategic Vision

Provide a summary of your company/organization’s short term and long term goals and strategic vision.

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## Miscellaneous

Please enter your response to each requirement using the guidelines provided in the tables below. If additional documentation or schematics are required to respond to a particular question, please answer the question as succinctly and accurately as possible and reference supplemental attachments.

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# Company/Organization Response to RFI (*to be completed by RFI respondent)*

## Proposal

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## Functional Requirements & Specifications

Refer to the following Functional Requirements and Specifications checklist which summarizes the collective requirements and specifications by the member companies participating in the project.

Based upon your proposed approach to deliver a solution, provide a response to each checklist item along with comments and assign one of the following Codes to each item:

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| A | Current capability of existing product |
| B | Able to add capability as requested |
| C | Able to add capability with modification to ETC request |
| D | Unable to add capability |

| Feature | Requirement | Code | Vendor Comments |
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## Estimated Timeline

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## Estimated Project Cost

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal, participating ETC members will provide resources in the form of funding and subject matter expertise to support the development of this project.  While ETC will entertain all proposals received, regarding funding from ETC, please consider the following:

* When partnering with a commercial vendor, any monetary resources provided by ETC should be viewed as seed funding to supplement the total development costs with the collaborator investing as well;
* For academic or non-profit partnerships, any monetary contributions by ETC will be for the total project costs, inclusive of indirect costs.

Please describe below project costs, including not only the total project costs but also costs to be paid by ETC and any costs borne by your organization.

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## Commercialization and Support

The overarching goal of ETC is to help bring innovative technologies to the commercial marketplace in partnership with third parties.  Aligned with that goal ETC looks to collaborate on projects which will result in products that are commercially available and supported in the marketplace.  With most projects, all commercialization rights will reside with the collaborator; ETC will not assume ownership of any intellectual property (IP) developed by the collaborator or expect royalties from future commercial sales.

Please describe your organization’s plans for commercialization and support of this technology following the successful conclusion of this project.  If your organization is not a commercial entity (e.g., academic or non-profit), please describe any plans related to the availability of the technology following the successful conclusion of the project.

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# APPENDIX A

ETC has been made aware of the following patents from Amgen, one of the members of ETC. The information provided below is for informational purposes only. Respondents are not required nor encouraged to use any of the patented technology or techniques provided below in their response to this RFI. In addition, ETC makes no guarantee there is not additional existing intellectual property beyond what is listed below from Amgen or other sources. As stated in Section 1.7.1., it is the responsibility of the respondent to conduct an intellectual property search and take all necessary steps to ensure their proposed project will not infringe or misappropriate any intellectual property right of a third party and/or obtain all necessary consents, assignments and licenses to provide the solution in the project proposal.

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**I.** The following Amgen patent application family relates generally to detection of undissolved particles in fluid. This patent application family is potentially relevant to instruments for the automated detection of visible particles. Any determinations of relevance to any instrument will depend on the actual patent claims in an applicable jurisdiction and the characteristics of the instrument under consideration.

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| PCT Pub. No. WO 2013/033253Publication Date: 2013-03-07“Methods and apparati for nondestructive detection of undissolved particles in a fluid” |
| **Abstract**: The apparati, methods, and computer program products disclosed herein can be used to nondestructively detect undissolved particles, such as glass flakes and/or protein aggregates, in a fluidin a vessel, such as, but not limited to, a fluid that contains a drug. |
| *Granted patents in Australia, Canada, China, Israel, Japan, Korea, Russia, Singapore, Taiwan, and United States* |
| *Pending patent applications in Canada, Eurasia, Europe, Hong Kong, Israel, Japan, Korea, Taiwan, and United States* |
| Granted US Patent: | Sample Claim |
| US 9922429 | 1. A method for nondestructive detection of an undissolved particle in a vessel that is at least partially filled with a fluid, the method comprising: (a) using at least one imager to image the particle; (b) processing the image to determine position data indicative of a position of the particle in the vessel; (c) detecting the particle based at least in part on the position data, wherein detecting the particle based at least in part on the position data comprises identifying the presence of the particle in a sub-region of the vessel; (d) using a sensor to determine a characteristic of the particle when the particle is located in the sub-region of the vessel, (e) generating particle characteristic data indicative of the determined characteristic; and (f) associating the particle characteristic data with data identifying the particle. |
| US 9892523 | 1. An apparatus for nondestructive detection of an undissolved particle in a vessel that is at least partially filled with a fluid, the apparatus comprising: at least two imagers positioned to image the particle from different perspectives, each imager from among the at least two imagers configured to respectively acquire one or more two dimensional images of the particle in the fluid; a memory operably coupled to the imager and configured to store the two dimensional images; and a processor operably coupled to the memory and configured to detect the particle by: combining the two dimensional images from the at least two imagers to determine three dimensional position data indicative of a position of the particle in the vessel; and detecting the particle based at least in part on the three dimensional position data, wherein the processor is configured to, when the three dimensional position data comprises at least one blind spot region corresponding to a region of the vessel not imaged by the at least two imagers, determine blind spot trajectory information indicative of a path of the particle in the blind spot region based at least in part on a time-series of two dimensional images of the particle from one of the at least two imagers. |
| US 9418416 | 1. A method of nondestructive counting and sizing of undissolved particles in a vessel that is at least partially filled with a fluid, the method comprising: (a) receiving, by a sensor of an imaging system, at least one image of the particles in the vessel obtained under specified imaging conditions; and analyzing the at least one image by a processor of the imaging system, the analyzing including (b)-(d): (b) detecting the particles and determining information indicative of an apparent size of the detected particles in the image; (c) determining apparent particle size population information indicative of an apparent particle size distribution of the detected particles; and (d) determining actual particle size population information indicative of an actual particle size distribution of the detected particles based on: (i) the apparent particle size population information; and (ii) calibration population information indicative of the apparent size distribution of one or more sets of standard sized particles imaged under conditions corresponding to the specified imaging conditions; wherein (d) comprises fitting a superposition of apparent size distributions for a plurality of the sets of standard sized particles to the apparent particle size population of the detected particles; and wherein fitting the superposition of apparent size distributions for the plurality of sets of standard sized particles conditions to the apparent particle size population of the detected particles comprises: minimizing a difference between the superposition and the apparent particle size population of the detected particles by adjusting the weighting of the apparent size distributions for the plurality of sets of standard sized particles. |
| US 9842408 | 1. A method of nondestructive counting and sizing of undissolved particles in a vessel that is at least partially filled with a fluid, the method comprising: capturing, via an imager, at least one image of the particles in the vessel that has been imaged under specified imaging conditions; storing, via a processor coupled to a memory, the at least one image in the memory; analyzing, via the processor, the at least one image to detect the particles and to calculate information indicative of the apparent size of the detected particles in the at least one image; calculating, via the processor, apparent particle size population information indicative of a distribution of varying apparent particle sizes of the detected particles in the at least one image; and calculating, via the processor, actual particle size population information indicative of a distribution of varying actual particle sizes of the detected particles in the at least one image based on a comparison between: (i) the apparent particle size population information; and (ii) calibration population information indicative of a distribution of varying apparent particle sizes of one or more sets of standard sized particles imaged under conditions corresponding to the specified imaging conditions. |
| US 10832433 | 1. An apparatus for nondestructive detection of an undissolved particle in a vessel that is at least partially filled with a fluid, comprising: a sensor; an imager configured to acquire one or more images of the particle in the fluid, the imager comprising at least one imaging optical element positioned to image the particle onto the sensor; and an illumination source positioned to illuminate contents of the vessel for imaging by the imager while substantially eliminating a presence of light rays emitted from the illumination source that reflect or refract from a surface of the vessel and are imaged by the at least one optical element onto the sensor. |

**II.** In addition, Amgen has several patent application families that relate generally to methods and systems for enhancing the performance of optical inspection. Any determinations of relevance to any instrument will depend on the actual patent claims in an applicable jurisdiction and the characteristics of the instrument under consideration. These patent application families include:

| **Publication Number** | **Title** | **Abstract** | **Publication Date** |
| --- | --- | --- | --- |
| WO2018044328*See, also* US Pat No:US9704239 | VIDEO TRIGGER SYNCHRONIZATION FOR IMPROVED PARTICLE DETECTION IN A VESSEL | A method includes, during an agitation period of an agitation profile, applying a motion to a transparent vessel containing a fluid, and while applying the motion; acquiring a sequence of original images of a portion of the transparent vessel; generating a background image from the sequence of original images; generating a resultant image from the background image and an original image in the sequence of original images; and identifying from the resultant image a particle in the fluid. | 2018-03-08 |
| WO2018147858*See, also* US Pat. Nos:US10088660US10539773 | IMAGING SYSTEM FOR COUNTING AND SIZING PARTICLES IN FLUID-FILLED VESSELS | A system is described to facilitate the characterization of particles within a fluid contained in a vessel using an illumination system that directs source light through each vessel. One or more optical elements may be implemented to refract the source light and to illuminate the entire volume of the vessel. As the refracted source light passes through the vessel and interacts with particles suspended in the fluid, scattered light is produced and directed to an imager, while the refracted source light is diverted away from the imager to prevent the source light from drowning out the scattered light. The system can therefore advantageously utilize an imager with a large depth of field to accurately image the entire volume of fluid at the same time, facilitating the determination of the number and size of particles suspended in the fluid. | 2018-08-16 |
| WO2019190647 | CAMERA-BASED DRUG CONTAINER INSPECTION | An inspection system for a drug container is provided to identify foreign matter, such as particles or fibers, within the drug container prior to filling with a drug. The system includes a camera device aligned with an axis of the drug container and captures a series of images of an interior surface of a sidewall of the drug container while the robot causes relative movement between the drug container and the camera device along a linear path. Atypical lighting, which improves contrast between particles and the background in images is employed to aid detection. A control circuit then processes the series of images to identify foreign matter within the drug container. | 2019-10-03 |
| WO2020027923 | ROBOTIC SYSTEM FOR PERFORMING PATTERN RECOGNITION-BASED INSPECTION OF PHARMACEUTICAL CONTAINERS | A robotic inspection platform comprises a robotic arm, an imager, and a controller. The controller causes the robotic arm to retrieve, using its end effector, a container, and to manipulate the container such that the container is sequentially placed in a plurality of orientations while in view of the imager. The controller also causes the imager to capture images, with each of the images being captured while the container is in a respective one of the orientations. The controller also determines one or more attributes of the container, and/or a sample within the container, by analyzing the images using a pattern recognition model and, based on the attribute(s), determines whether the container and/or sample satisfies one or more criteria. If the container and/or sample fails to satisfy the criteria, the controller causes the robotic arm to place the container in an area (e.g., bin) reserved for rejected containers and/or samples. | 2020-02-06 |
| WO2020068298 | IMAGE SAMPLING FOR VISUAL INSPECTION | A method for sampling images includes receiving a first image set generated by automated imaging equipment during a first inspection period, and storing in a memory an image library that initially consists of the first image set. A plurality of new image sets is then sequentially received (302) during respective inspection periods. While the new image sets are received (302), the image library stored in the memory is updated. Updating the image library includes, for each new image set, adding to the image library a certain number of images distributed among the new image set and removing from the image library the same number of images distributed among a current instance of the image library (308). The number of overwritten images in the image library decreases from one inspection period to the next. | 2020-04-02 |
| WO2020131662 | APPARATUS FOR RESOLVING IMAGING PROBLEMS CAUSED BY THE MENISCUS | A well plate cover includes a base defining a base plane, and a plurality of insertion elements. At least a portion of each of the insertion elements is transparent. Each of the insertion elements is coupled to the base, and extends, in a direction orthogonal to the base plane, from the base to a distal end surface of the insertion element. The distal end surface of each of the insertion elements includes an apex that, when the respective insertion element is inserted into a well of a well plate, extends further into the well than any other portion of the distal end surface. The apex is a point, a line, or a plane having a diameter that is less than one half of a maximum diameter of the distal end surface. | 2020-06-25 |
| WO2020131666 | SHEET LIGHTING FOR PARTICLE DETECTION IN DRUG PRODUCT CONTAINERS | In a method for imaging a container holding a sample, the container is illuminated with a laser sheet that impinges upon the container in a first direction corresponding to a first axis. A plane of the laser sheet is defined by the first axis and a second axis orthogonal to the first axis. The method also includes capturing, by a camera having an imaging axis that is substantially orthogonal to at least the first axis, an image of the container. The method further includes analyzing, by one or more processors, the image of the container to detect particles within, and/or on an exterior surface of, the container. | 2020-06-25 |
| WO2020247357 | 3D PARTICLE IMAGING IN PHARMACEUTICAL CONTAINERS | A method for 3D imaging of a sample, in a vessel having a longitudinal axis orthogonal to a horizontal plane, includes capturing, by at least three cameras located at different positions around the vessel, respective 2D images of the sample. Each image comprises pixels having associated pixel values. The optical axis of a first camera is inclined or declined at a first angle relative to the horizontal plane, with the first angle being greater than or equal to zero degrees. The optical axis of a second camera is inclined or declined at a second, larger angle relative to the horizontal plane. The method also includes generating a 3D image of the sample based on the pixel values associated with the 2D image pixels, and one or more look-up tables that collectively indicate, for pixels in each image, expected paths for light traversing the vessel and the sample. | 2020-12-10 |

**III.** In the event a company is interested in licensing any of the technology listed above as part of this project, Amgen has informed ETC that they would be amenable to licensing its intellectual property relating to automated particle analysis in the field of offline laboratory scale automated particle analysis instruments. Amgen would expect a royalty commensurate with the innovation it has contributed to the field.