Question	BGTD Response
For Group 4 products, if periodic testing is requested by BGTD, is the Sponsor required to wait for a Release Letter issuied by BGTD?	Yes. If lot samples have been requested by BGTD for periodic testing, the targeted timeframe for release is 6 weeks from the date that all required information is received.
Are DIN-B products subject to the Lot Release Programme?	Yes. DIN-B products are subject to the Lot Release Program.
Can you comment on the criteria for moving from Grp 2 to Grp 3? Are some products ineligible for such a move?	Usually, with the exception of prophylactic vaccines, products remain in group 2 for a period of one year, or until such time as five lots have been tested and released, whichever is longest. Following the one year period or period where five lots have been tested satisfactorily, the product may be re-assigned into group 3 or 4 providing there have been consistent and reliable testing outcomes observed while in group 2 and that there have been no changes in the manufacturing process that may have an impact on the quality of the product. Typically prophylactic vaccines are not eligible for movement from group 2 to group 3.
Can a sponsor justify within an NDS if their product falls within a certain category? Is there an opportunity to appeal a classification?	Yes. Upon the assignment or re-assignment of a product into an evaluation group, the sponsor may appeal the lot release evaluation group decision in writing to the Director of CBE or CERB. BGTD targets 60 calendar days to assess the submitted information and provide a written response to the sponsor.
Are there specific timelines for when a Sponsor should anticipate sample requests prior to NOC decision date?	No. There are no specific timelines.
Will BGTD move group classification to lower risk (e.g. group 3 to 4) without sponsor's request?	Yes. BGTD can move the group classification to lower risk without the sponsor's request.

What is the BGTD target timelines associated with a change in group (i.e. timeline for BGTD review of change request for group 2 to group 3)?	BGTD will respond to formal requests to appeal the lot release group assignment within 60 calendar days.
Is there a certain number of lots that need to be provided to show consistency for re-classification?	Usually, with the exception of prophlylactic vaccines, products remain in group 2 for a period of one year, or until such time as five lots have been tested and released, whichever is longest. Following the one year period or period where five lots have been tested satisfactorily, the product may be re-assigned into group 3 or 4 providing there have been consistent and reliable testing outcomes observed while in group 2 and that there have been no changes in the manufacturing process that may have an impact on the quality of the product.
In the case of vaccines, does the manufacturer have any input in the decision to move from group 2 to group 3 (i.e. can the manufacturuer request a review)?	Yes . Manufacturers may apply for re-assignment, in writing and provide the data outlined in Section 5.1 of the *Guidance for Sponsors: Lot Release Program for Schedule D (Biologic) Drugs* to the Director of CBE or CERB in order to be assessed for re-assignment into a different evaluation group.
Is the BGTD QMS Annual Report available to Sponsors? If yes, how can Sponsor's obtain access?	The BGTD management review annual report is not publicly available. However,information related to the performance monitoring of the lot release program can be made avaliable upon request.
What does accredited test methods means?	Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Accreditation to the ISO/IEC 17025 standard requirements ensures that procedures, facilities and analytical methods which are in the scope of the accreditation conform to ISO/IEC 17025, the internationally recognized standard. Such accreditation demonstrates a technical competence of the accredited laboratory for the performance of its analytical methods and generated results.

are there other options to send the "faxback" other than through the fax machine? can the documents be emailed to specific email address?	Yes. Fax-Backs may also be sent by email to BERU-URES@hc-sc.gc.ca
For YBPR review, we have recently received the confirmation from BGTD of YBPR 2010 review being complete. Is there a back log in YBPRs review?	Please note that the YBPRs do not have a mandated review target. The target that appears in DSTS was determined by the Lot Release Working Group when the guidance document was finalized in 2005 and is not meant to be tracked as backlog; just as an indication of work to be done. While BGTD may have lagged in formally documenting the review of YBPRs this does not mean that they have not been used in the interim to provide clarification on the state of control of products, or to support decision making on lot release activities, or during submission review.
Why doesn't BGTD issue release for bulk fill instead of labeled finished lot? This was a former BGTD practice.	Lot release is issued for labeled finished lots because it can be used to identify a lot in distribution in the Canadian market as well as to trace the lot in manufacture . The ability to both identify a drug lot in distribution and to trace it in manufacture is critical to Health Canada's responsiblities throughout the product life-cycle including pre- and post-market surveillance activities (e.g. adverse event reporting and monitoring) as well product compliance and enforcement activities (e.g. product recalls). It is for these reasons that BGTD does not issue release for bulk fill lots.

Given HC is an associated member of EDQM OMCL and information regarding lots are shared, is there any future possibilty that HC will leverage EU final lot release information to support lot release in Canada?	BGTD does not plan to leverage EU final lot release information to support lot release in Canada on a routine basis. However, BGTD will continue to leverage this information in certain circumstances to support lot release activities.
In the case of vaccines, can the manufacturer request that material is released as the bulk as opposed to the final container?	No. Refer to previous answer to "Why doesn't BGTD issue release for buk fill instead of labeled finished lot? This was a former BGTD practice".
How soon during the review can the sponsor find out the lot release category?	Although the formal lot release evaluation group assignment is not communicated until the end of the submission review, BGTD would be in a position to informally communicate the lot release evaluation group assignment witin the last 30 days of the submission review period for a new drug submission. That said, it can generally be expected that prophylactic vaccines will be assigned to evaluation group 2, recombinant biotherapeutics will be assigned to evaluation group 4 and naturally sourced biotherapeutics to evaluation group 3.
In terms of the testing, is it based on the manufacturer's release testing specifications? And does the manufacturer need to provide special reagents in certain cases?	Yes. Typically lot release testing is based on the manufacturer's release testing specifications and the manufacturer may be required to provide special reagents such as reference materials, antibodies, etc., in certain cases. These requirements will be communicated to the sponsor by BGTD either in the form of a clarifax in the case of consistency testing or in a post-decision letter in the case of an NDS or SNDS.

How and when do you use foreign test data in lot release?	Within the post-approval evaluation groups, test data from foreign regulatory authorities is used in the lot release evaluation in the following circumstances: 1) BGTD lacks the necessary expertise and/or equipment to perform the test, 2) the number of lots distributed in Canada is too few to justify in-house sample testing 3) to support decisions to reject or recall lots in Canada, 4) to verify and/or compare results or trends observed in BGTD test results. In the case of pre-approval consistentcy lots, test data from foreign regulatory authorities is not typically available as consistency testing is not routinely performed by other regulatory authorities.
Will BGTD continue to harmonize with the EU towards the acceptance of EU OMCL test results for lot release?	No. BGTD does not plan to move towards the acceptance of EU OMCL test results in lieu of in-house testing under the lot release program.
How many staff are involved in lot release? Seems only 3 blood product lots were rejected in 2013. Would it be reasonable to restrict this program to blood products and vaccines only?	Lot Release is an integrated activity along with submission review that forms part of the life-cycle management of the quality aspects of Biologic Products in Canada. As such, there are 85 BGTD staff members who contribute to the program function in some way as part of their daily responsibilities. The current lot release program provides a level regulatory oversight which is appropriate to the degree of risk assoicated with each biologic product.

How would fax-back lot release work for an autologous vaccine to treat cancer that is manufactured for an individual patient?	With respect to clinical trial materials, the fax-back process for an autologous vaccine to treat cancer that is manufactured for an individual patient would be dependant on the nature of the vaccine itself. For example, in the case where the personalized vaccine consists of purified antigens or proteins from autologous cells of an individual subject and the final product formulation is stable (e.g 3 month shelf-life), the standard fax-back process for group 1A clinical trial materials would be applied. In the case where the personalized vaccine consists of autologous whole cells from an individual subject with an extremely short shelf-life (e.g. 24 hours), the sponsor would be required to complete and submit the fax-back form but would not be required to await a signed response from BGTD prior to use of the material in the approved clinical trial.
Does BGTD have any plans to move any viral vaccines from Group 2 to Group 3?	No. BGTD does not have plans to systematically move viral vaccines from group 2 to group 3. The movement of a viral vaccine to group 3 is possible and has been done for at least two viral vaccines recently.